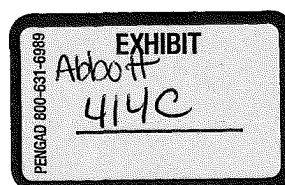


EXHIBIT N

THIRD AMENDED COMPLAINT

**Filed on or About
December 9, 1999**



UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
SOUTHERN DIVISION

UNITED STATES OF AMERICA)
Ex Rel)
VEN-A-CARE OF THE)
FLORIDA KEYS, INC.)
a Florida Corporation,)
by and through its principal)
officers and directors,)
ZACHARY T. BENTLEY and)
T. MARK JONES,)
Plaintiff,)

v.)

ABBOTT LABORATORIES, INC.;)
)

CIVIL ACTION NO.95-1354-CIV-GOLD

FILED IN CAMERA AND UNDER SEAL

THIRD AMENDED COMPLAINT
For Money Damages and Civil
Penalties Under the False Claims Act
31 U.S.C. §§3729-3732

CIVIL ACTION NO. 95-1354-CIV-GOLD

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]


[REDACTED], (sometimes referred to collectively as, "DEFENDANTS"), for money damages and civil penalties arising out of the DEFENDANTS' violations of the Federal False Claims Act, 31 U.S.C., §§3729-3732 from on or about June 23, 1989 to the present date.

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SECTION NO. 1

SUMMARY OF THE ACTION

1. This is an action for damages, treble damages, civil penalties and costs against the DEFENDANTS for violations of the False Claims Act as set out in Counts I through VII, pages 299 through 314. In essence, the DEFENDANTS made false representations of prices and costs for certain of their [REDACTED], injectable and [REDACTED] drugs [REDACTED] (hereinafter sometimes referred to as the "specified infusion drugs")

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or the "specified drugs"): directly to Medicare Carriers who approve and pay Medicare claims; directly to the States' Medicaid Pharmacy Programs which approve and pay the States' Medicaid claims; and indirectly through drug price and cost reporting compendia including First Data Bank, Medical Economics, and Medi-Span. The DEFENDANTS knew that the Medicare and States' Medicaid Programs intended to base their payments of "reimbursement" for the specified infusion drugs on reasonable estimations of cost. The Medicare and Medicaid Programs relied on the prices reported by the DEFENDANTS in estimating costs. The DEFENDANTS marketed their specified infusion drugs to specialized physicians [REDACTED] clinics and infusion pharmacies, including the Relator's, through financial inducements, including but not limited to, false price markups (the "Spread"), discounts, free goods and other financial incentives. The DEFENDANTS were in a position to mislead the Medicare and Medicaid Programs because the DEFENDANTS typically report truthful prices for their other drugs that are not the subject of this action. The DEFENDANTS thus wrongfully exploited the Medicare and States' Medicaid Programs by causing them to pay the claims of the DEFENDANTS' customers at grossly inflated amounts that far exceeded a reasonable reimbursement based on an estimation of costs. The DEFENDANTS' false claims scheme damaged the Medicare and States' Medicaid Programs in excess of ONE BILLION and 00/100 DOLLARS (\$1,000,000,000.00).

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SECTION NO. 2

THE PARTIES

2. The Plaintiff in this action is the UNITED STATES. At all times material to this civil action, the United States Department of Health and Human Services ("HHS"), the Health Care Financing Administration ("HCFA"), and The Bureau of Program Operations ("BPO") were agencies and instrumentalities of the UNITED STATES and their activities, operations and contracts in administering the Medicare program were paid from UNITED STATES' funds. The UNITED STATES and its subcontractors performing on behalf of the UNITED STATES provided Medicare benefits to qualified beneficiaries which included payment of claims for the prescription drugs specified herein manufactured by the DEFENDANTS and relied upon the false and fraudulent price and cost representations made by the DEFENDANTS in approving and paying claims.

3. The States, United States Territories, and the District of Columbia provided Medicaid benefits to qualified recipients which included payment of claims for the prescription drugs specified herein manufactured by the DEFENDANTS and relied upon the false and fraudulent price and cost representations made by the DEFENDANTS in

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approving and paying claims. A significant part of said Medicaid reimbursement was paid from United States Government funds pursuant to **42 U.S.C. § 1396(b)**.

4. The Relator, VEN-A-CARE, is a corporation organized under the laws of the State of Florida, with its principal offices in Key West, Florida. The Relator's principal officers and directors include Zachary T. Bentley and T. Mark Jones, who are each citizens of the United States and reside in Key West, Florida. The Relator is an infusion pharmacy and provides prescription drugs, such as the intravenous, injectable [REDACTED] [REDACTED] specified in this Third Amended Complaint, as a Medicare Part B supplier and as a Florida Medicaid provider. The Relator has direct and independent knowledge of the information, and is the "original source" of the information on which these allegations are based within the meaning of **31 U.S.C. §3730(e)(4)(A) and (B)**. The Relator has standing to bring this action pursuant to **31 U.S.C. §3730(b)(1)**. The information upon which these allegations are based was voluntarily provided by the Relator to the Federal Government beginning in 1991 and thereafter has been frequently supplemented by the Relator.

5. The Relator, VEN-A-CARE, is a small infusion pharmacy located in Key West, Florida that, due to its position as an industry insider, became aware of the false claim scheme alleged herein. During the early 1990s, Ven-A-Care was destroyed as a viable business because it refused to engage in fee splitting arrangements with referring physicians who wished to benefit from the inflated reimbursement caused by the actions

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of the DEFENDANTS. Ven-A-Care became aware that many of the [REDACTED], inhalation, and injectable drugs [REDACTED] it provided as a specialty pharmacy were reimbursed by the Medicare and Medicaid Programs at amounts that substantially, in some cases by several thousand percent, exceeded the cost of the drug. It was the huge potential profit spreads generated by the variance between the actual cost of the drugs and the "reimbursement" amounts that many referring physicians demanded a share of. Ven-A-Care's principals were aware that Medicare and Medicaid reimbursed for drugs at amounts that were intended to be based on an estimation of cost and not provide for huge windfall profits at the GOVERNMENT's expense. Ven-A-Care attempted to alert the responsible state and federal government officials to the problem it faced. However, the government agencies lacked sufficient resources and expertise to adequately respond. Accordingly, the Relator commenced this action based upon its original source information.

6. The Defendant, ABBOTT LABORATORIES, INC. ("ABBOTT"), is a corporation organized under the laws of Delaware, with its principal offices in Abbott Park, Illinois. At all times material to this civil action, ABBOTT has transacted business in the Federal Judicial District of the Southern District of Florida by, including, but not limited to, selling and distributing prescription drugs to purchasers within the Southern District of Florida.

7. [REDACTED]
[REDACTED]

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**PAGES 15 THROUGH 23
HAVE BEEN COMPLETELY REDACTED
WHICH INCLUDES THE REMAINDER OF
PARAGRAPH 7
THROUGH THE BEGINNING OF PARAGRAPH 32**

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[REDACTED]

33. Any and all acts alleged herein to have been committed by any or all of the DEFENDANTS were committed by said Defendant's officers, directors, employees, or agents who at all times acted on behalf of their respective DEFENDANT.

SECTION NO. 3

JURISDICTION & VENUE

34. Jurisdiction is founded upon the **Federal False Claims Act, (the "Act")** 31 U.S.C. §3729-32, specifically 31 U.S.C. §3732, and also 28 U.S.C. §§1331, 1345.

35. The Federal False Claims Act reaches the type of fraudulent activity alleged herein in accordance with the express language of the Act as well as precedents arising from applications of the present Federal False Claims Act and earlier versions, See, United States v. Neifert-White Company, 390 U.S. 228; 88 S.Ct. 959 (1968). Specifically, the

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United States Supreme Court's application of the Act in Neifert-White applies to this case as follows:

A. ". . . the Act was intended to reach all types of fraud, without qualification, that might result in financial loss to the Government." 88 S.Ct., at 961.

B. The Act applies to the conduct of a manufacturer that supplies falsely inflated price information in support of a customer's claim. 88 S.Ct., at 960.

C. The Act applies even where the price information supplied by the DEFENDANTS is inflated by only approximately 25% over the truthful price. 88 S.Ct., at 960.

D. The Act applies even if the DEFENDANTS did not submit the false price information directly to the Government and even though the DEFENDANTS received no payment of funds from the Government.

E. The Act applies even though the inflated portion of the price was received by customers of the DEFENDANTS who are not parties to the case. 88 S.Ct., at 960.

36. Venue in the Southern District of Florida is appropriate under **31 U.S.C. §3732(a)** and sufficient contacts exist for jurisdiction in that each of the DEFENDANTS transacted business in the Southern District of Florida by selling directly or through wholesalers their specified prescription drugs in the Southern District of Florida which the respective DEFENDANTS knew would be supplied to Medicare beneficiaries and Medicaid

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recipients and for which the DEFENDANTS knew that grossly excessive and unreasonable payments for claims would be made to the providers/suppliers by the Medicare and Medicaid programs.

37. A copy of the initial Complaint and Amended Complaints and written disclosure of substantially all material evidence and information VEN-A-CARE possesses were served on the Government pursuant to Rule 4(d)(1), Fed.R.Civ.P., prior to the filing of the initial and Amended Complaints in camera and under seal by delivering a copy of the summons, Complaints, material evidence and information to the United States Attorney for the Southern District of Florida and by sending a copy of the summons, Complaints, material evidence and information by certified mail to the Attorney General of the United States at Washington, District of Columbia. Thereafter the Relator has continued its investigation of the matters herein and has diligently and expeditiously provided any and all documentary and other evidence to the Office of the Attorney General of the United States and to the Office of the United States Attorney for the Southern District of Florida prior to filing this Third Amended Complaint. A copy of the Third Amended Complaint was served in the manner required by law on the Attorney General and on the United States Attorney for the Southern District of Florida prior to filing with the Court.

38. The Relator alleges: (A) that no allegation or transaction of defrauding the United States was made prior to the filing of the Complaints in public disclosures regarding the subject matter herein against any of the DEFENDANTS; (B) that none of the

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DEFENDANTS was named in public disclosures made prior to the filing of the Complaints regarding the subject matter herein; and (C), if the Court makes a finding against the Relator as to the allegations set forth in (A) and/or (B), that the Relator has direct and independent knowledge of the information on which these allegations are based within the meaning of **31 U.S.C. §3730(e)(4)(A) and (B)** and has voluntarily provided the information to the Government before filing the Complaints which are based on the information provided by the Relator to the Government and the Relator is the original source.

39. Federal Court jurisdiction also exists over this cause for reasons which include, but are not limited to, the following:

A) The RELATOR and its principal officers and directors have sustained significant injury and damage due to the acts of the DEFENDANTS in that referring physicians, and others able to influence the ordering of infusion pharmacy services, typically demand a portion of the financial inducements created by the DEFENDANTS' false price representations in exchange for referrals. The RELATOR, a one time profitable business, has refused to engage in such conduct and, as a result, has been unable to compete in its chosen health care market.

B) The RELATOR, due to its status as an industry insider, has acquired substantial information that is of significant value to the Government about the DEFENDANTS' false claim scheme and has provided said information to the Government in accordance with the False Claims Act.

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C) The RELATOR has expended substantial time, money and resources, and has incurred substantial financial and other risks in reviewing its own information and in acquiring, analyzing and disclosing to the Government its information about the DEFENDANTS' false claims scheme, prior to commencing this action.

D) The remedies provided by the False Claims Act include, in part, an award to the RELATOR for providing to the Government the information about the DEFENDANTS' false claim scheme that is at issue in this action. In order to secure redress of its right to such award, the RELATOR has complied with the requirements of the False Claims Act that it initiate this action under seal and disclose all its information to the Government.

E) This False Claims Act case constitutes the only lawful mechanism whereby the RELATOR may receive redress in the form of compensation for providing information about the DEFENDANTS' false claim scheme and for assisting the Government in recovering amounts paid, multiple damages and penalties.

F) The False Claims Act provides a mechanism whereby the RELATOR may secure redress for its cause of action, to wit, its right to compensation for benefitting the Government through use of its information about the False Claims scheme in the manner contemplated by the False Claims Act.

G) The RELATOR is also entitled, under the False Claims Act, to litigate the Government's right to damages and penalties, arising from the false claim scheme and

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has a stake in the outcome in that the RELATOR is entitled by the False Claims Act to share in any recovery secured by or on behalf of the Government.

H) The relief provided under the False Claims Act is designed, in part, to deter future violations and the false claim scheme alleged herein is ongoing and continues to impede the RELATOR'S ability to lawfully compete and is likely to continue in the future absent the RELATOR'S exercise of its rights and responsibilities as a realtor under the False Claims Act.

I) The deterrent impact of a judgment under the False Claims Act will act to redress the injuries sustained by the RELATOR, and limit or curtail future injuries to the RELATOR, due to the DEFENDANTS' ongoing false claims scheme.

J) The DEFENDANTS each possess a substantial interest in disproving the RELATOR'S allegations of violations of the False Claims Act and the RELATOR possesses a substantial interest in proving said allegations, as well as the investment of the RELATOR's costs and its overall compliance with the pre filing and post filing procedural and jurisdictional provisions of the False Claims Act, because the determination of these issues under the False Claims Act will establish whether:

- (i) The DEFENDANTS violated the federal False Claims Act;
- (ii) The DEFENDANTS are liable for treble damages, penalties, costs, RELATOR's expenses and attorneys fees.

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- (iii) The RELATOR is entitled to redress in the form of compensation for providing its information about the false claims scheme to the Government and for assisting the Government in the manner required by the False Claims Act;
- (iv) The RELATOR is entitled to redress, on behalf of the Government, in the form of damages and penalties from the DEFENDANTS.
- (v) The RELATOR is entitled to redress in the form of its relator's share of the award of damages and penalties.
- (vi) The RELATOR is entitled to redress in the form of compensation for its expenses , incurrence of risk, and investment of time and resources in acquiring and providing to the Government its information about the false claims scheme.
- (vii) The RELATOR is entitled to redress in the form of the deterrent impact of a False Claims Act judgement, against one or more DEFENDANTS, on the ongoing and future conduct of the DEFENDANTS that has injured and continues to injure the RELATOR as alleged herein.

K) In the event that the Government intervenes with respect to some or all of the RELATOR'S allegations and claims, then the RELATOR is entitled to participate

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in the litigation to the extent and under the conditions specified in the False Claims Act and to further pursue redress in the form of its right to share in any award and receive compensation for its costs and expenses.

L) In the event that the Government does not intervene with respect to some or all of the RELATOR's allegations and claims, then the RELATOR'S causes of action alleged herein are directed at further redress in that only by prevailing in litigation based on its information about the false claim scheme will the RELATOR be able to seek: redress in the form of deterrence of ongoing and future conduct injurious to the RELATOR; compensation for its information about the DEFENDANTS' false claim scheme; compensation for the assistance and benefit it provided to the Government; compensation for its expenses, risks and devotion of time and resources in acquiring and providing its information to the Government; and compensation for establishing the DEFENDANTS' liability for damages and penalties.

SECTION NO. 4

**HOW MEDICARE AND MEDICAID REIMBURSEMENT IS AFFECTED BY
DRUG MANUFACTURERS' PRICE AND COST REPRESENTATIONS**

40. Drug manufacturers, including the DEFENDANTS, the Medicare and Medicaid Programs, drug price and cost reporting services, hospitals, pharmacies, physicians, wholesalers, third party payors and administrators (i.e. insurance companies),

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governmental health benefit plans (i.e. federal and state employees) and others involved in the health care industry communicate about drug prices and costs by describing the price and cost with terms such as:

- a) Average Wholesale Price ("AWP")
- b) Wholesaler Acquisition Cost ("WAC")
- c) List Price
- d) Direct Price ("DP")
- e) Wholesale Net Price

41. Of the above terms, Average Wholesale Price, or AWP, is most utilized by the healthcare industry and by third party payors including the Medicare and Medicaid Programs to describe the average price of a drug sold to a retailer (i.e. Physicians, Hospitals and Pharmacies) who then provides the drug to its ultimate recipient.

42. During the time covered by this complaint until January 1 1998, Medicare based its reimbursement for prescription drugs, including the drugs at issue, on the manufacturers' published AWP for patented ("single source") drugs as represented by the manufacturer, and at the median published AWP, as represented by the manufacturers, for drugs with generic equivalents and for biologicals. From January 1, 1998 until the present, Medicare has based its reimbursement for drugs at 95% of the published AWP for single source patented drugs as represented by the manufacturer, and at 95 % of the

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median published AWP, as represented by the manufacturers, for drugs with generic equivalents and for biologicals.

43. The States' Medicaid programs are required by 42 CFR 447.331 to reimburse providers at the provider's Estimated Acquisition Cost ("EAC"). The Health Care Financing Administration ("HCFA"), which must approve all State reimbursement plans for prescription drugs, has approved approximately 38 state plans whose methodology for arriving at the provider's EAC includes discounting a percentage off of the published AWP prices. This discounting ranges from Alaska, whose state formula is AWP minus 5%, to Michigan, whose state formula is AWP minus 13.5 - 15.1 %. Nineteen states' formulas are AWP minus 10%. Seven states' formulas are WAC plus a percentage or an AWP discount/WAC hybrid. The State of Delaware bases reimbursement on the providers' actual acquisition cost ("AAC"). The balance of the states use a EAC/AWP discount mix.

44. The Office of Personnel Management administers health insurance for all Federal employees. Benefits and reimbursements for prescription drugs are based upon the published AWP's as represented by the drug manufacturers.

45. The Department of Defense's CHAMPUS program, now known as Tricare, bases benefits and reimbursements for prescription drugs upon the published AWP's as represented by the drug manufacturers.

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46. The Relator's investigation has determined that most private third party health insurers also use the published AWP's as represented by the drug manufacturers in establishing prices for prescription drug benefits.

47. The drug manufacturing industry, including the DEFENDANTS, uses various forms of media to publicize the prices and cost of their drugs including but not limited to:

- a) Direct mailings or electronic communications (i.e. fax or e-mails) to hospitals, pharmacies, physicians, the States' Medicaid programs and the Medicare Carriers;
- b) Advertisements in bi-monthly medical publications, such as :
 - (i) *Medical Economics*, that is mailed bi-monthly to most physicians and hospitals, free of charge by its publisher; and
 - (ii) *Drug Topics*, that is mailed bi-monthly to most pharmacies and hospitals, free of charge by its publisher;
- c) *PDR Generics* published annually by Medical Economics, Inc. who also publishes *The Physicians Desk Reference* ("PDR")
- d) Advertisements provided directly to physicians and pharmacists by drug companies' representatives.

48. The Relator's information provided to the Government demonstrates the common and wide spread use of the term "Average Wholesale Price" (AWP) to describe

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drug prices in a manner whereby interested parties can make decisions that are affected by price, including but not limited to:

a) Representative examples of advertisements routinely delivered by some of the DEFENDANTS and Non-Defendant drug manufacturers directly to individual State Medicaid Programs that were delivered to the State of New Jersey's Medicaid Pharmacy Program.

b) Representative examples of advertisements routinely delivered by the DEFENDANTS and Non-Defendant drug manufacturers directly to individual Medicare Carriers responsible for approving and paying Medicare claims in the States of Florida and Utah.

c) Representative examples of direct mail advertisements sent to the Relator by Non-Defendant drug companies expressing their respective drug prices in terms of AWP.

d) Representative examples of advertisements that the DEFENDANTS caused to be published in *Medical Economics* that express their respective drug prices in terms of AWP.

e) Representative examples of advertisements that the respective drug manufacturers caused to be published in *Drug Topics* that express their respective drug prices in terms of AWP.

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f) Representative examples of the publisher's representations about the 1996 edition of *PDR Generics*, which contains representations about drugs at issue in this case including price and cost information expressed in terms of AWP. The advertisement also states that *PDR Generics* provides physicians and other health care professionals with "cost of therapy tables" that enable the physician to compare cost of therapies. The cost of therapies are based upon the manufacturers' published AWP's for the respective drugs.

49. Drug manufacturers including some of the DEFENDANTS also represent drug prices in terms of AWP when comparing the price and cost of their drugs to the prices and costs of their competitors' drugs. These comparisons of prices are promoted to physicians, pharmacists and hospitals touting that one company's drug is less costly than that of its competitors.

50. Medical Economics, Inc., the Hearst Corporation and Medi-Span are nationally recognized companies that specialize in gathering drug pricing and cost information including Average Wholesale Price ("AWP"), Wholesaler Acquisition Cost ("WAC") and Direct Price ("DP").

51. Medical Economics, Inc. publishes annually a book entitled *Drug Topics Red Book* that expresses drug prices and costs in terms of AWP. Representative examples of *Drug Topics Red Book* for the years 1991, 1992, 1993, 1994, 1995, 1996, 1997, 1998

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and 1999 contain approximately the following number of pages expressing drug prices and costs in terms of AWP:

- a) 1991 - 605 pages
- b) 1992 - 575 pages
- c) 1993 - 542 pages
- d) 1994 - 331 pages
- e) 1995 - 369 pages
- f) 1996 - 413 pages
- g) 1997 - 454 pages
- h) 1998 - 470 pages
- i) 1999 - 454 pages

52. Medical Economics also provides addendums to the annual *Red Book* that express drug prices and costs in terms of AWP.

53. Representative excerpts of advisements contained in the annual *Reb Book* publications for the years 1995, 1996, 1997, 1998 and 1999 include:

- a) The 1995 advertisement describes the price information as "nationally recognized average wholesale prices (AWPs, direct prices and federally upper limited prices for prescription drugs)."

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b) The 1996 advertisement states "nationally recognized Average Wholesale Prices (AWPs), Direct Prices and Federal Upper Limit prices for prescription drugs that help you make sure your prices are on-target."

c) The 1997 advertisement states "complete pricing information: AWP's, direct and suggested retail prices."

d) The 1998 advertisement states "RED BOOK is the first and only source of accurate, up-to-date product information, prices on prescription drugs, OTC items and reimbursable medical supplies and more!"

e) The 1999 advertisement states "nationally recognized Average Wholesale Prices (AWPs), Direct Prices and Federal Upper Limit prices for prescription drugs that help you make sure your prices are on-target."

54. Medical Economics, Inc. also publishes a monthly update that contains current packaging and pricing data expressed in terms of AWP on the most widely prescribed drugs in the United States together with any updated prices expressed in terms of AWP for new products.

55. The Relator's information provided to the Government reveals that approximately 90% of the Medicare Carriers use the AWP's as represented in Medical Economics annual *Drug Topics Red Book* publication and the *Red Book* monthly updates in determining the reimbursement amounts for Medicare prescription drug claims.

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56. The Hearst Corporation published until 1997 annually a book entitled *the Blue Book* that expressed drug prices and costs in terms of AWP. Representative examples of the *First Databank Blue Book* for the years 1990, 1991, 1992, 1993, 1994, 1995 and 1996 contain approximately the following number of pages expressing drug prices and costs in terms of AWP:

- a) 1990 - 498 pages
- b) 1991 - 492 pages
- c) 1992 - 482 pages
- d) 1993 - 402 pages
- e) 1994 - 755 pages
- f) 1995 - 391 pages
- g) 1996 - 432 pages

57. First Data Bank also publishes a monthly update entitled "Price Alert" that expresses drug prices and costs in terms of AWP.

58. First Data Bank also provides drug prices and costs for approximately 60,000 different drugs, sizes and strengths expressed in terms of AWP and WAC through an electronic or automated service. The Relator's investigation has determined that more than 90% of the States' Medicaid Pharmacy Programs utilized the AWP's and WACs as represented by First Data Bank's automated services in determining reimbursement amounts for Medicaid prescription drugs and claims.

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Economics to the Medicare and States' Medicaid Programs at all times at issue in this action. The Relator reported its information to the Government, including specific identification of representatives of First Data Bank and Medical Economics to whom such information was reported. Thereafter, the Government conducted an investigation which confirmed the information supplied by the Relator.

A. The Government's investigation revealed that each of the DEFENDANTS has repeatedly and systemically communicated with First Data Bank and Medical Economics for the express purpose of causing First Data Bank and Medical Economics to report prices and costs of the drugs at issue in this case in amounts set by the DEFENDANTS.

B. The Government's investigation secured documentary information between the DEFENDANTS and First Data Bank and Medical Economics wherein the DEFENDANTS caused specific prices and costs for their drugs to be reported by First Data Bank and Medical Economics.

68. The DEFENDANTS' fraudulent inflation of price and cost information to cause the Government to pay excessive reimbursement for the specified drugs at issue is in stark contrast to the truthful representations that the DEFENDANTS make when they are not offering financial inducements to their customers.

69. Unlike the specialized physicians, clinics and infusion pharmacies which receive the financial inducements for ordering the drugs at issue in this action, most

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INJ, IJ (M.D.V.)			
20 mg/ml, 5 ml.....	00013-7336-91	136.49	AP
10 ml.....	00013-7346-94	272.98	AP
25 ml.....	00013-7356-88	665.38	AP

b) The Carrier arrays the listings from the most expensive to the least expensive of all the manufacturers' generics (in this case [REDACTED] is the Brand so it is not included) that list a 100 mg. size (20 mg/ml, 5 ml = 100mg.).

Gensia)			
(M.D.V.)			
20 mg/ml, 5 ml.....	00703-5643-01	141.97	= \$ 141.97 ea.
(Schein)			
INJ, IJ (M.D.V.)			
20 mg/ml, 5 ml.....	00364-3028-53	141.50	= \$ 141.50 ea.
(Supergen)			
INJ, IJ (M.D.V.)			
20 mg/ml, 5 ml.....	58406-0711-12	141.00	= \$ 141.00 ea.
TOPOSAR (Pharmacia/Upjohn)			
etoposide			
INJ, IJ (M.D.V.)			
20 mg/ml, 5 ml.....	00013-7336-91	136.49	= \$ 136.49 ea.
(Bedford)			
INJ, IJ (M.D.V.)			
20 mg/ml, 5 ml.....	55390-0291-01	110.00	= \$ 110.00 ea.
Astra USA)			
INJ, IJ (VIAL)			
20 mg/ml, 5 ml 10s ..	00186-1571-31	387.50	= \$ 38.75 ea.

c) The Carrier then finds the median AWP. In this instance the median is between [REDACTED]

[REDACTED] The Relators investigation has determined

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that some Medicare Carriers choose the higher listing of the median and some choose the lower.

80. Part B drug claims are submitted in one of two ways. The first is by submitting to the Part B carriers or DMERCs a completed (hard copy) HCFA 1500 Form. The second is through an electronic claims filing procedure whereby the same information required to be included on the hard copy HCFA 1500 Form is transmitted to the Medicare Part B carriers or DMERCs. Two HCFA 1500 Form versions were used during the time relevant to these proceedings. HCFA Form 1500 (1/84) was used by the Medicare program for Part B drug claims filed on or after January, 1984. In or about December 1990, HCFA created HCFA Form 1500 (12/90) and required its use for drug claims submitted on or after May 1, 1992. Either HCFA Form 1500 (12/90) or HCFA Form 1500 (1/84) could be used for Part B drug claims from December, 1990 through April, 1992.

81. Providers submit claims for payment to the Medicare Program for the specified drugs at issue in this case using HCFA's Common Procedure Coding System ("HCPCS"). The HCPCS system for pharmaceuticals is a 5 digit alphanumeric code, such as Leucovorin, 50 mg. = HCPCS Code J0640.

82. HCFA requires all Part B Carriers and the DMERCs to report to HCFA Central quarterly claims activity by HCPCS Code for all drugs submitted by providers for reimbursement by the Medicare Program. This quarterly data collected by HCFA Central

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from all the Part B Carriers and the DMERCs is summarized in a report known as the Part B Extract and Summary System ("BESS") or Bess Reports.

83. Beneficiaries' claims are processed by the carriers as either "assigned", those claims for which payment is made directly to the provider, or "unassigned", those claims for which payment is made directly to the beneficiaries.

84. All or nearly all drug claims for the charges at issue are made on an assigned basis.

85. During the early 90's the Medicare Carriers' attempted to survey physicians' actual invoice prices paid for drugs to comply with the regulation 42 CFR §405.517 but were stopped by a complaint filed by the American Society of Clinical Oncologists ("ASCO") with the Executive Office of Management and Budget asserting that the Paperwork Reduction Act had been violated. A subsequent effort by HCFA to design a new survey to determine physicians' actual invoice costs was also stopped by ASCO. ASCO complained that the actual prices being paid were discounts and confidential in nature and that the survey had other flaws.

86. At all times at issue in this case, the Medicare program used the drug price and cost information represented by the DEFENDANTS to determine reimbursement amounts.

SECTION NO. 6

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**BACKGROUND OF HOW UNITED STATES' MONIES
ARE PAID FOR DRUG CLAIMS UNDER
THE STATES' MEDICAID PROGRAMS**

87. The United States Government partially funds state sponsored medical assistance programs for the poor pursuant to **Title XIX of the Social Security Act, 42 U.S.C. § 1396 et seq.**

88. Benefits for drugs are optional but all states have opted to provide Medicaid drug reimbursement coverage.

89. The federal portion of States' Medicaid payments, Federal Medical Assistance Percentage ("FMAP") is based on a state's per capita income compared to the national average. The federal portion consists of a minimum of 50% up to a maximum of 83%. By example, Florida's FMAP contributed by the United States in 1995 was 56.28%.

90. The States, United States Territories and the District of Columbia are required to implement a State Health Plan containing certain specified minimum criteria for coverage and payment of claims in order to qualify for federal funds for Medicaid expenditures. **42 U.S.C. §1396a(a)(30)(A).**

91. State Health Plans must, in part, provide for payment of claims for prescription drugs pursuant to a formula approved by the Secretary of HHS which determines the maximum allowable claim amount for each drug manufactured by each manufacturer whose prescription drugs qualify for Medicaid reimbursement based upon

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an estimation of the provider's acquisition cost plus a reasonable dispensing fee. 42 CFR 447.331.

92. HCFA has approved approximately 38 state plans whose methodology for arriving at a provider's Estimated Acquisition Cost ("EAC") as required by 42 CFR 447.331 includes discounting a percentage off of the AWP prices, separately for each covered drug, as computed by or collected by and published by First Data Bank. This discounting ranges from Alaska, whose state formula is AWP minus 5%, to Michigan, whose state formula is AWP minus 13.5 - 15.1 %. Nineteen HCFA approved states' formulas are on a basis of AWP minus 10%. Seven states' formulas are WAC plus a percentage or an AWP discount/WAC hybrid. The State of Florida's formula is WAC plus 7%. The State of Delaware bases reimbursement on AAC.

93. The Food and Drug Administration ("FDA") assigns National Drug Codes, NDC numbers to identify each individual manufacturer and its drugs' strengths and sizes. NDC numbers are eleven digits, with the first five digits identifying the manufacturer or labeler, the next four digits identifying the product and the last two digits identifying the package size.

94. Providers are required to utilize the FDA's NDC numbers when submitting claims for reimbursement for drugs to the States' Medicaid programs.

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95. The vast majority of States award cost-reimbursement contracts to private companies to evaluate and process Medicaid recipients' claims for payment. The States refer to these contractors as fiscal agents.

96. Prescription drug claims are submitted in one of two ways. The first is by submitting to the fiscal agent or state agency a completed (hard copy) pharmacy claim form. The second is through an electronic claims filing procedure whereby the same information required to be included on the hard copy is transmitted electronically to the Medicaid fiscal agent or state agency.

97. At all times at issue in this case, all of the States' Medicaid programs used the drug price and cost information represented by the DEFENDANTS to determine reimbursement amounts.

SECTION NO. 7

THE FALSE CLAIMS SCHEME

98. The DEFENDANTS are each liable under the False Claims Act because they caused the Medicare and Medicaid Programs to pay claims for certain of their prescription drugs in exorbitant amounts, far in excess of the reasonable reimbursement permitted under the applicable statutes and regulations. The DEFENDANTS manufactured and/or distributed the specified prescription drugs in this action and sold the specified prescription drugs either directly to specialized infusion pharmacies, physicians, clinics and others or indirectly through such intermediaries as wholesalers and group purchasing organizations.

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The false claims for excessive reimbursement were then submitted to the Medicare and the States' Medicaid Programs by the DEFENDANTS' through their false price and cost statements and by their customers who thereby received a windfall financial benefit in the amount by which the Government's approved "reimbursement" exceeded a reasonable estimate of acquisition cost.

99. The DEFENDANTS also caused the submission of false claims by actively marketing their specified drugs to their customer providers by the use of financial inducements created by "the spread" between the DEFENDANTS' true prices to their customers and the Medicare and the States' Medicaid Programs reimbursements based on the DEFENDANTS' falsely inflated prices reported to Medicare and the States' Medicaid Programs and their subcontractors. The financial inducements were in many cases enhanced by additional inducements such as free goods, discounts, rebates, direct money payments, off invoice pricing and deceptive invoicing.

100. The DEFENDANTS knew that the Medicare and States' Medicaid Programs would not pay or approve claims for the specified drugs if it were disclosed to the Medicare and States' Medicaid Programs that said claims were for amounts that included illegal remuneration prohibited by the anti-kick back statutes, 42 U.S.C. §1320a-7b(b)(2) and 1395nn(a)(1)(B).

101. The DEFENDANTS also knew that their customers, in presenting claims for the specified drugs to the Medicare and States' Medicaid Programs, would not and did not

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disclose that the claim amounts included the remuneration prohibited by 42 U.S.C. §1320a-7b(b)(2) and 1395 nn(a)(1)(B).

102. The DEFENDANTS each carried out their scheme to defraud the Government by knowingly providing false and misleading price and cost information to the Medicare and Medicaid Programs so that the specialized pharmacies, physicians and others submitting the claims would be reimbursed in excessive amounts and thus be financially induced to prescribe and purchase the DEFENDANTS' specified drugs. The DEFENDANTS thus each participated in a fraudulent scheme to cause the Government to pay and approve false claims in excessive amounts.

103. The claims in question are each false claims under the False Claims Act, in part, because they were each supported by, and the payment amount determined due to the Government's use of, the false and misleading price and cost information provided by the DEFENDANTS in connection with their respective specified drugs. The false and misleading price and cost information provided by the DEFENDANTS was material in that the information was used in setting Medicare and Medicaid reimbursement amounts and each DEFENDANT acted knowingly, as defined in the False Claims Act, in providing the false and misleading price and cost information that caused the Government to pay claims for the DEFENDANTS' drugs in excessive amounts. The price and cost information provided by the DEFENDANTS was provided to cause the Government to pay amounts based on the information and thus constitutes claims submitted to the Government.

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104. The false claims at issue in this action were each submitted to the Medicare and Medicaid Programs by or on behalf of physicians, specialized pharmacies and others that sought and received payment in excessive amounts because of false and misleading price and cost representations made by the DEFENDANTS directly or indirectly to the Medicare and Medicaid Programs. The specific false claims are thus each and every claim submitted to the Medicare or Medicaid Program for which the payment amount was determined by use, in whole or to any degree, of the false and misleading price representations of the DEFENDANTS. The false claims at issue number in the tens of thousands and each claim is in the possession of a state's Medicaid Program or Medicare Carrier to which it was submitted. The Relator has identified the specific false claims to the Government by providing the truthful prices concealed from the Government by the DEFENDANTS for each drug, providing information about the DEFENDANTS' exploitation of financial inducements to induce utilization of the specified drugs and specific identification information about the prescription drugs and the specific false price representations in question from which the Relator and the Government identified the specific false claims.

105. The damages sought herein include, but are not limited to, those arising from the false claims for the specified drugs set out in Sections 8 through 32 and elsewhere throughout this Third Amended Complaint. The false claims for the specified drugs set out herein are alleged to meet the specificity and particularity requirements for pleading

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under the Federal Rules of Civil Procedure. The damages sought herein encompass all damages and penalties recoverable due to the false claim scheme of the DEFENDANTS alleged herein relating to all drugs of all sizes about which false price and cost representations or records were used in connection with, considered or made available in, caused, aided or otherwise affected the presentment, payment or approval of false claims. These claims also encompass recovery of the funds paid for false claims due to the DEFENDANTS' false drug price and cost representations, regardless of the Government program that actually expended the funds, the person or entity that ultimately received the funds or the person or entity from which the United States ultimately recovers the funds.

Subsection 7a.

**The Unique Kinds of Drugs, Patient/Physician Relationships,
and Drug Wholesale Distribution Systems That Make The
False Claims Scheme Possible**

106. The Medicare beneficiaries and Medicaid recipients who receive the prescription drugs at issue are usually extremely ill and suffer from such diseases and conditions as [REDACTED]

[REDACTED]

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107. The specified prescription drugs at issue in this case are a special kind that are usually administered by [REDACTED], injection or [REDACTED] and are not readily available through normal retail pharmacies but are instead provided directly by hospitals, physicians, clinics and specialized pharmacies and home health care providers.

108. The prescription drugs at issue, like all prescription drugs, may only be provided to a patient upon the order of a physician.

109. Prescription drugs provided outside of the hospital setting are ordinarily sold by community retail pharmacies (i.e. Walgreens, Eckerd's and neighborhood independent drug stores) directly to the patient. Typically a patient is provided a prescription for a particular drug by a physician. The patient takes the prescription and independently decides at which pharmacy the prescription will be filled. Thus, the prescribing physician has no financial incentive or financial inducement to prescribe a particular drug or recommend a drug as the therapy of choice over that of a possible alternative therapy.

110. This case, however, focuses on a different and distinct type of prescription drug which cannot be taken by mouth and generally is not self administered. The specified prescription drugs are generally administered to the patient by a professional (i.e. a nurse) intravenously, by injection [REDACTED]. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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115. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

116. The specialized physicians often are in unique relationships with the DEFENDANTS in that the physicians not only prescribe the specified drugs, but also directly administer or arrange for their administration and often then submit claims for them or have a financial relationship with the entity submitting the claim.

117. The DEFENDANTS have also developed special wholesale delivery systems for the drugs at issue in this case in order to facilitate the financial inducements for those in a position to cause the DEFENDANTS' respective drugs to be ordered for patients and paid for by Medicare, Medicaid or other Government programs.

118. The majority of the DEFENDANTS' drugs, not at issue in this action, are distributed through drug wholesalers who resell and distribute the drugs to hospitals, pharmacies, physicians and clinics.

119. Four companies, McKesson Drug, Cardinal, Bergen Brunswig and Ameri-Source comprise approximately eighty (80%) of the 53 billion dollar annual wholesale drug market. Except for the specified drugs, the DEFENDANTS do not generally dictate to these wholesalers who they may sell to or at what price they may sell at. Wholesalers

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generally sell to any person or entity (i.e. pharmacies, physicians and hospitals) who can lawfully purchase prescription drugs.

120. Wholesalers purchase the specified drugs at issue in this case at prices that are unilaterally set and controlled by the DEFENDANTS. The wholesalers in turn add a percentage (commonly referred to as an "up-charge") to the price that they pay the DEFENDANTS. The "up-charge", which is an amount usually approved by the DEFENDANT selling the specific drug, covers the wholesaler's expenses such as warehousing, delivery, billing and collections and provides a profit.

121. The DEFENDANTS also enter into what are known as "charge-back " arrangements with wholesalers whereby the drugs at issue in this case are sold to the wholesaler at a fictitiously inflated price and then the wholesaler is credited by the DEFENDANT for the difference between the fictitious price and the true price to the DEFENDANTS' customer plus the agreed "up charge" for the wholesaler. The "charge-back" scheme allows the DEFENDANTS to utilize the services of the wholesalers while establishing prices for their drugs to their select customers/providers.

122. The "charge-back" scheme is illustrated by the following example of the drug,

[REDACTED]

[REDACTED] and wholesaled through McKesson Drug Co.

("McKesson");

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- a) McKesson's 1998 wholesale price for [REDACTED], is \$109.19 plus an up-charge.
- b) Ven-A-Care is a member of the Greater New York Hospital Association's ("GNYHA") group purchasing organization.
- c) Ven-A-Care's GNYHA contract price for [REDACTED] is \$10.00 plus the wholesaler up-charge. VAC's up-charge from McKesson is 7%, therefore, VAC can purchase [REDACTED] from McKesson for \$10.70 which is \$98.49 less than McKesson paid.
- d) McKesson claims a "charge-back" from [REDACTED] of \$99.19 which represents the difference in price from what McKesson paid versus what McKesson sold it to VAC for plus McKesson's up-charge.

123. The DEFENDANTS also sell the specified drugs to other wholesalers which they sometimes refer to as "distributors", "specialty wholesalers" or "oncology supply houses". These wholesalers sell the specified drugs to select providers (i.e. specialized physicians and closed pharmacies) at prices that are sometimes a mere fraction of the fictitious prices purported to be paid, before charge-back credit, by McKesson, Cardinal, Bergen Brunswig and Ameri-Source. These other wholesalers include Oncology Therapeutics Network ("OTN") a wholly owned subsidiary of [REDACTED] BRISTOL-MYERS SQUIBB, Florida Infusion, Alternate Site Distributors "ASD" (a subsidiary of Bergen Brunswig), National Specialty Services ("NSS") (a subsidiary of Cardinal) and

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Oncology Supply (a subsidiary of Bergen Brunswig). Their primary business involves selling infusion, injectable and biological drugs. These wholesalers sell many of the drugs at issue in this case; however, the prices are generally net and do not include any wholesaler up-charge. Unlike McKesson Drug, Cardinal, Bergen Brunswig and Ameri-Source who determine their own customers, the DEFENDANTS dictate and control who specialty wholesalers such as OTN, Florida Infusion, NSS, ASD, Oncology Supply may sell to and at what price they may sell.

124. In order to monitor the wholesalers' compliance, the DEFENDANTS require all drug wholesalers to periodically (generally quarterly) report back to the DEFENDANTS all prescription drug sales by NDC number, provider name and sales price.

125. A representative example of the DEFENDANTS' practice was demonstrated when VAC was informed by a [REDACTED] sales representative that [REDACTED] and other drug manufactures consider this information vital in determining how and where to market their prescription drugs. The [REDACTED] representative informed VAC that [REDACTED] prepared reports for every sales representative based on the information compiled from all wholesalers reports and that the [REDACTED] report was broken down by postal zip code, provider, NDC number, quantity and sales prices.

126. The DEFENDANTS negotiate prices for their prescription drugs individually with hospitals, Government entities, closed pharmacies, mail order pharmacies, HMO's, physicians, and with group purchasing organizations ("GPO's") who represent groups of

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smaller providers. GPO's provide members lower cost products by negotiating prices for specific drugs from manufacturers. The GPO member is able to purchase the drugs at the negotiated price either in some cases directly from the manufacturer or from a wholesaler that has a charge-back agreement with the specific manufacturer. All of the wholesalers have participated to some degree in the DEFENDANTS' charge-back system. Like the determination by the DEFENDANTS as to who OTN, Florida Infusion, NSS, ASD, Oncology Supply may sell to, acceptable membership in the GPOs is controlled by the DEFENDANTS. The GPO's are required to send periodic detailed reports of membership compliance to the DEFENDANTS.

Subsection 7b.

**The Medicare and Medicaid Programs Use
The Defendants' False and Misleading Price and Cost
Representations to Estimate the Acquisition Cost of
The Specified Drugs in Setting Reimbursement Amounts**

127. The Medicare and Medicaid Programs are each structured so that covered prescription drugs are reimbursed on an estimated cost basis while physicians and other health care providers are reimbursed separately for their professional services and are not

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entitled to receive any form of financial incentive or inducement for prescribing or delivering drugs.

128. The Medicare and Medicaid Programs use the price and cost representations of the DEFENDANTS in order to estimate acquisition cost in setting reimbursement amounts.

129. The DEFENDANTS' price and cost representations are provided to the Medicare and Medicaid Programs directly and through drug price and cost information reporting services as alleged above.

130. The States' Medicaid Programs also receive price and cost representations directly from the DEFENDANTS and use them to confirm the accuracy of price and cost information used for computing reimbursement amounts.

131. **The Fraud on Medicare:** This case focuses, in part, on the specified drugs that are covered under Part B of the Medicare program which are sold and/or distributed by the DEFENDANTS and for which claims are paid by the Medicare Part B carriers and the DMERCs in amounts that are based in whole or in part on estimations of acquisition cost. The drugs at issue in this case, for which Medicare has paid claims, include but are not limited to those specified in the following table, together with their respective HCPCS codes. By way of example, the claim amount approved by the Florida Medicare Carrier for each drug in 1996, or in some instances 1997, if specified, is compared with the Relator's cost in order to illustrate the grossly excessive payments resulting from the

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DEFENDANTS' false representations of price and cost. The DEFENDANTS' false price and cost representations to the Medicare Program have resulted in claims being paid in exorbitant amounts in excess of the drug's cost as more specifically alleged in the following Table No. 1:

TABLE NO. 1

1(A) DEFENDANT ABBOTT						
DRUG	NDC #	HCPCS CODE	1996 FLORIDA MEDICARE ALLOWABLE	1996 RELATOR'S COST	PROVIDER'S GROSS PROFIT \$	PROVIDER'S GROSS PROFIT %
Sodium Chloride 0.9% 250 ml	00074-7983-02	J7050	\$9.43	\$0.95	\$8.48	892%
Sodium Chloride 0.9% 50 ml	00074-7983-03	J7040	\$10.14	\$0.95	\$9.19	967%
Sodium Chloride 0.9% 1000 ml	00074-7983-09	J7030	\$11.06	\$1.03	\$10.03	973%
5% Dextrose in Water w/5% etoh 500 ml	00074-7922-03	J7060	\$9.98	\$0.96	\$9.02	939%
5% Dextrose in Water 1000 ml	00074-7922-09	J7070	\$11.23	\$1.12	\$10.11	902%
Dextrose 5% with Sodium Chloride 0.9% 500 ml	00074-7941-03	J7042	\$10.24	\$1.03	\$9.21	894%
Ringers Lactate 1000 ml	00074-7953-09	J7120	\$12.43	\$1.14	\$11.29	990%
Vancomycin HCL 500 mg	00074-4332-01	J3370	\$12.91	\$3.51	\$9.40	267%

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1(A) DEFENDANT ABBOTT						
DRUG	NDC #	HCPCS CODE	1996 FLORIDA MEDICARE ALLOWABLE	1996 RELATOR'S COST	PROVIDER'S GROSS PROFIT \$	PROVIDER'S GROSS PROFIT %
Tobramycin Sulfate 80 mg	00074-3578-01	J3260	\$6.74	\$3.63	\$3.11	85%

1(B) [REDACTED]						
DRUG	NDC #	HCPCS CODE	1996 FLORIDA MEDICARE ALLOWABLE	1996 RELATOR'S COST	PROVIDER'S GROSS PROFIT \$	PROVIDER'S GROSS PROFIT %
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

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**PAGE 68 THROUGH PAGE 80
HAVE BEEN COMPLETELY REDACTED**

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[REDACTED]						
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]						
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]						
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

132. **The Fraud on Medicaid:** This case, in part, focuses on the specified drugs that are covered under the States' Medicaid Programs which are sold and/or distributed by the DEFENDANTS and for which the States' Medicaid Programs paid claims in amounts that are based in whole or in part on estimations of acquisition cost. The drugs at issue in this case for which Medicaid has paid claims are identified in the following table,

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together with their respective NDC numbers. By way of example, the claim amount approved by Florida Medicaid for each drug in 1996 (unless specified as 1997) is compared with the Relator's cost in order to illustrate the grossly excessive payments resulting from the DEFENDANTS' false representations of price and cost. The DEFENDANTS' price and cost representations to the States' Medicaid Programs have resulted in claims being paid in exorbitant amounts in excess of the drug's cost as more specifically alleged in the following Table No. 2:

TABLE NO. 2

2(A) DEFENDANT ABBOTT					
DRUG	NDC #	FLORIDA MEDICAID PAYMENT	RELATOR'S COST	PROVIDER'S GROSS PROFIT \$	PROVIDER'S GROSS PROFIT %
Sodium Chloride 0.9% 50 ml	00074-7101-13	\$11.28	\$1.23	\$10.05	817%
Sodium Chloride 0.9% 100 ml	00074-7101-23	\$11.28	\$1.23	\$10.05	817%
Sodium Chloride 0.9% 250 ml	00074-7983-02	\$9.37	\$0.95	\$8.42	886%
Sodium Chloride 0.9% 500 ml	00074-7983-03	\$9.37	\$0.95	\$8.42	886%
Sodium Chloride 0.9% 1000 ml	00074-7983-09	\$11.16	\$1.03	\$10.13	983%
5% Dextrose in Water 50 ml	00074-7100-13	\$11.28	\$1.23	\$10.05	817%

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2(A) DEFENDANT ABBOTT					
DRUG	NDC #	FLORIDA MEDICAID PAYMENT	RELATOR'S COST	PROVIDER'S GROSS PROFIT \$	PROVIDER'S GROSS PROFIT %
5% Dextrose in Water 100 ml	00074-7100-23	\$11.28	\$1.23	410.05	817%
5% Dextrose in Water 250 ml	00074-7100-02	\$13.67	\$1.33	\$12.34	928%
5% Dextrose in Water 500 ml	00074-7922-03	\$9.53	\$0.96	\$8.57	892%
5% Dextrose in Water 1000 ml	00074-7922-09	\$11.13	\$1.12	\$11.01	983%
5% Dextrose/ Sodium Chloride 0.9% 250 ml	00074-7941-02	\$10.24	\$1.03	\$9.21	894%
5% Dextrose/ Sodium Chloride 0.9% 500 ml	00074-7941-03	\$10.23	\$1.03	\$9.20	893%
5% Dextrose/ Sodium Chloride 0.9% 1000 ml	00074-7941-09	\$12.51	\$1.23	\$11.28	917%
Ringers Lactate 250 ml	00074-7953-02	\$11.34	\$1.08	\$10.00	926%
Ringers Lactate 500 ml	00074-7953-03	\$11.34	\$1.08	\$10.26	950%
Ringers Lactate 1000 ml	00074-7953-09	\$12.72	\$1.14	\$11.58	915%

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2(A) DEFENDANT ABBOTT					
DRUG	NDC #	FLORIDA MEDICAID PAYMENT	RELATOR'S COST	PROVIDER'S GROSS PROFIT \$	PROVIDER'S GROSS PROFIT %
Vancomycin HCL 500 mg	00074-4332-01	\$30.85	\$3.51	\$27.34	779%
Vancomycin HCL 500 mg	00074-6535-01	\$22.19	\$6.29	\$15.90	252%
Vancomycin HCL 1 gm	00074-6533-01	\$61.68	\$5.53	\$56.15	1015%
Vancomycin HCL 5 gm	00074-6509-01	\$138.76	\$35.10	\$103.66	295%
Tobramycin Sulfate 20 mg	00074-3577-01	\$4.86	\$1.94	\$2.92	150%
Tobramycin Sulfate 60 mg	00074-3582-01	\$6.21	\$3.68	\$2.53	68%
Tobramycin Sulfate 60 mg	0074-3469-13	\$21.45	\$5.16	\$16.29	315%
Tobramycin Sulfate 60 mg	00074-3254-03	\$16.04	\$3.97	\$12.07	304%
Tobramycin Sulfate 80 mg	00074-3470-23	\$23.45	\$5.57	\$17.88	321%
Tobramycin Sulfate 80 mg	00074-3583-01	\$10.26	\$4.12	\$6.14	149%
Tobramycin Sulfate 80 mg	00074-3578-01	\$9.64	\$3.63	\$6.01	165%
Tobramycin Sulfate 80 mg	00074-3255-03	\$10.72	\$4.33	\$6.39	147%
Tobramycin Sulfate 2000 mg	00074-3590-02	\$241.07	\$87.68	\$153.39	174%
Pentamidine 300 mg	00074-4548-01	\$111.40	\$43.00	\$68.40	159%

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2(A) DEFENDANT ABBOTT					
DRUG	NDC #	FLORIDA MEDICAID PAYMENT	RELATOR'S COST	PROVIDER'S GROSS PROFIT \$	PROVIDER'S GROSS PROFIT %
Clindamycin Phosphate 300 mg	00074-4053-03	\$11.07	\$1.74	\$9.33	536%
Clindamycin Phosphate 300 mg	00074-4050-01	\$10.99	\$1.47	\$9.52	647%
Clindamycin Phosphate 600 mg	0074-4054-03	\$20.35	\$2.95	\$17.40	589%
Clindamycin Phosphate 600 mg	00074-4051-01	\$21.34	\$2.69	\$18.65	693%
Clindamycin Phosphate 900 mg	00074-4052-01	\$26.96	\$3.20	\$23.76	742%
Clindamycin Phosphate 900 mg	00074-4197-01	\$221.11	\$30.95	\$190.16	614%
Clindamycin Phosphate 900 mg	00074-4055-03	\$27.22	\$3.46	\$23.76	686%
Sodium Bicarbonate 50 ml	00074-6625-02	\$6.57	\$0.62	\$5.95	959%
Sodium Bicarbonate 8.4% 50 ml	00074-6637-01	\$18.28	\$1.66	\$16.62	1001%
Amikacin Sulfate 500 mg, 2 ml	00074-1958-01	\$55.18	\$15.50	\$39.68	256%
Amikacin Sulfate 100 mg, 2 ml	00074-1955-01	\$40.20	\$11.50	\$28.70	249%

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2(A) DEFENDANT ABBOTT					
DRUG	NDC #	FLORIDA MEDICAID PAYMENT	RELATOR'S COST	PROVIDER'S GROSS PROFIT \$	PROVIDER'S GROSS PROFIT %
Amikacin Sulfate 1 gm, 4 ml	00074-1957-01	\$49.81	\$28.50	\$21.31	75%
Heparin Lock Flush 10u/ml, 30 ml	00074-1151-78	\$2.86	\$0.38	\$2.48	652%
Heparin Lock Flush 100u/ml 30 ml	00074-1152-78	\$3.26	\$0.44	\$2.82	640%
Heparin Lock Flush 100u/ml 10 ml	00074-1152-70	\$1.40	\$0.28	\$1.12	400%
Water for Inj. 20 ml	00074-4887-20	\$1.72	\$0.23	\$1.49	647%
Water for Inj. 10 ml	00074-4887-10	\$1.37	\$0.19	\$1.18	621%
Water for Inj. 30 ml	00074-3977-03	\$1.84	\$0.20	\$1.64	820%
Water for Inj. 1000 ml	00074-1590-05	\$11.34	\$1.13	\$10.21	903%
Water for Inj. 1000 ml	00074-7990-09	\$10.27	\$1.04	\$9.23	887%
Water for Inj. 100 ml	00074-4887-99	\$3.42	\$0.71	\$2.71	381%
Dex 5%/ Kcl/NaCl 1000 ml	00074-7902-09	\$17.46	\$2.05	\$15.41	751%
Furosemide 40 mg 4 ml	00074-6102-04	\$4.13	\$0.35	\$3.78	1080%

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[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]					
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

133. The representations of their drugs' prices made by the DEFENDANTS to First Data Bank, Medical Economics, Medi-Span and directly to the Medicare carriers and the States' Medicaid Programs are material for the establishment of reasonable reimbursements by Medicare and the States' Medicaid Programs. The importance that drug manufacturers represent truthful costs and prices and how these representations

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affect reimbursements in both States whose formula is WAC plus a percentage and States whose formula is AWP minus a percentage is demonstrated by the following example:

■ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

■ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

■ [REDACTED]

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■ [REDACTED]

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[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

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[REDACTED]									
[REDACTED]		[REDACTED]		[REDACTED]		[REDACTED]		[REDACTED]	
[REDACTED]		[REDACTED]		[REDACTED]		[REDACTED]		[REDACTED]	
[REDACTED]		[REDACTED]		[REDACTED]		[REDACTED]		[REDACTED]	
[REDACTED]		[REDACTED]		[REDACTED]		[REDACTED]		[REDACTED]	
[REDACTED]		[REDACTED]		[REDACTED]		[REDACTED]		[REDACTED]	

Subsection 7c.

The Defendants Each Determine What Representations Will Be Made to the Drug Price and Cost Reporting Compendia and To the Medicare and Medicaid Programs, Have Knowledge of the Actual Prices of Their Drugs, and Know If the Government Is Being Provided with False and Misleading Price and Cost Information

134. The DEFENDANTS are prohibited by the False Claims Act from making false representations in connection with claims for Government funds, are required by the Food and Drug Act to report true prices and are prohibited by the Medicare and Medicaid Anti-Kickback laws from arranging financial inducements for providers.

135. The patients and third party payers, including the Medicare and States' Medicaid Programs, are not aware of the prices actually paid for the specified drugs by the physician, clinic or specialty pharmacy presenting the claim for payment. The DEFENDANTS concealed from the Medicare and States' Medicaid Programs price

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reductions occurring due to competition in the marketplace and falsely and fraudulently represented drug prices that far exceeded the truthful prices.

136. At all times material to this action, each of the DEFENDANTS acted "knowingly" as that term is defined at 31 U.S.C. §3729(b) by:

- a) Causing the presentation of false and fraudulent claims for payment or approval by the Medicare and States' Medicaid programs; and
- b) Making and using false statements and/or records for the purpose of getting false or fraudulent claims approved or paid by the Medicare and States' Medicaid programs.

137. The DEFENDANTS were clearly placed on notice that their conduct would cause the Medicare and States' Medicaid programs to pay claims for the specified drugs in amounts exceeding that permitted by applicable law, in part, because:

- a) Each of the DEFENDANTS was on notice of federal statutes and regulations that limit payment of Medicare Part B claims for the specified drugs to 80% of a reasonable cost.
- b) Each of the DEFENDANTS was on notice of federal statutes and regulations limiting payment of Medicaid claims for the specified drugs to an amount necessary to cover the cost of the drug.

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c) Each of the DEFENDANTS was on notice that neither the Medicare nor the States' Medicaid programs were authorized or permitted by applicable law to pay claims for the specified drugs in excessive amounts.

d) Each of the DEFENDANTS was on notice that federal statutes and regulations prohibited them from making misleading representations about the specified drugs, including misleading price or cost representations.

138. Defendants ABBOTT, [REDACTED]

[REDACTED] repeatedly, systematically and falsely represented to the Medicare and States' Medicaid Programs that the prices of certain of their specified drugs were increasing or remaining substantially constant when they knew that in truth and in fact the prices had fallen substantially or were otherwise priced far below the represented prices and the Medicare and States' Medicaid Programs would pay and approve claims based on their false representations of the price of their drugs.

139. Each of the DEFENDANTS was on notice that federal statutes and regulations prohibited them from making misleading representations about the specified drugs, including misleading price or cost representations:

a) Each of the DEFENDANTS is required to comply with the Federal Food, Drug and Cosmetic Act 21 U.S.C. §321 et. seq., and the regulations promulgated pursuant thereto.

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b) The price and cost representations about the specified drugs constitute advertising that is included in the "labeling" provisions of the Federal Food and Drug Act and related regulations. 21 U.S.C. §§201(m); 202.1(k)(2).

c) Each of the DEFENDANTS is prohibited from disseminating any information about their prices or costs of the specified drugs that is "false or misleading in any particular . . ." 21 U.S.C. §§5.02; 302(b).

d) Each of the DEFENDANTS was on notice that they possessed a duty to assure that their representations about prices and costs of the specified drugs were not misleading, taking into account:

" . . . not only representations made or suggested by statement, word, design, device, or any combination thereof, but also to the extent to which the labeling or advertising fails to reveal facts material in light of such representations"

21 U.S.C. §201(n).

140. Notwithstanding the legislative intent of the Food Drug and Cosmetic Act, the DEFENDANTS, acting individually and in concert with one another, purposely created confusion and made false and misleading statements about drug pricing in order to deceive the United States Government and the States' Medicaid Programs. For several years, various Governmental agencies including the HHS Office of Inspector General "OIG" and the General Accounting Office "GAO" attempted to examine the issue of the reasonableness of reimbursements by the Medicare and States' Medicaid Programs for

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many of the drugs at issue in this Third Amended Complaint. The OIG's and GAO's efforts were thwarted, in part, by the DEFENDANTS withholding and concealing pertinent information that was being sought by the OIG and GAO. The OIG and GAO attempted through numerous published reports to identify the problem of unreasonable reimbursements; however, they were unsuccessful due to the actions of the DEFENDANTS. The DEFENDANTS concealed and disguised the unreasonable reimbursements from the United States Government and States' Medicaid Programs, in part, by the following facts and circumstances:

a) The DEFENDANTS can and do make truthful representations of price and costs for many of their drugs sold in retail community pharmacies and, in some instances, infusion, injectable and inhalation drugs and biologicals sold to physician groups, outpatient clinics and specialty infusion pharmacies.

b) Some drug manufacturers (other than the DEFENDANTS) make representations of costs and price only in terms of Average Wholesale Price "AWP".

c) Some of the DEFENDANTS make representations of cost and price only in terms of "List Price," "Wholesale Net," Direct Price "DP" or "DIRP," or Wholesaler Acquisition Costs, "WAC," to which Medical Economics and First Data Bank apply an industry average mark-up and establish an AWP.

d) Some of the DEFENDANTS make representations of cost and price in terms of both AWP and DP (or DIRP).

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141. **The Defendants Create the False Price Spread to Induce Sales of Drugs Used to Treat Very Serious Medical Conditions:** The following Table No. 3 lists each of the DEFENDANTS drugs and their approved FDA indications as published in the 1998 edition of *Drug Facts and Comparisons* and the percent of pricing fraud is represented by the mark-up between the DEFENDANTS AWP listing in the 1998 *Drug Topics* Red Book and Ven-A-Care's true 1998 wholesale cost for a common size.

TABLE NO. 3

<u>ABBOTT</u>		
<u>DRUG</u>	<u>F.D.A. APPROVED INDICATIONS</u>	<u>THE FALSE PRICE SPREAD</u>
Acyclovir (Antiviral)	HSV-1 and HSV-2 Varicella Zoster(Shingles) Herpes Simplex Encephalitis	363%
Amikacin (Antibiotic)	Bacterial Septicemia Respiratory Tract Infection Bone and Joint Infection Skin and Soft Tissue Infection Intra-abdominal Infection Burns Urinary Tract Infections	437%
Amino Acids/ Electrolytes (Nutrition)	Given to prevent nitrogen and weight loss and meet metabolic requirements when the gastrointestinal tract cannot be used or is inadequate.	1776%
Clindamycin (Antibiotic)	Respiratory Tract Infections Skin and Soft Tissue Infection Septicemia Female Pelvis and Genital Tract Infections Hematogenous Osteomyelitis	846%

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<u>ABBOTT</u>		
<u>DRUG</u>	<u>F.D.A. APPROVED INDICATIONS</u>	<u>THE FALSE PRICE SPREAD</u>
Dextrose 5% in Water (Fluid)	Intravenous Replenishment Solution	1562%
Dextrose 5% with Sodium Chloride (Fluid)	Intravenous Replenishment Solution	1014%
Dextrose 5% with Potassium and Sodium Chloride (Fluid)	Intravenous Replenishment Solution	2309%
Furosemide (Diuretic)	Edema Hypertension Acute Pulmonary Edema Congestive Heart Failure Chronic Renal Failure	3061%
Heparin (Anticoagulant)	Venous Thrombosis Pulmonary Embolism Peripheral Arterial Embolism	936%
Lactated Ringers (Fluid)	Intravenous Replenishment Solution	1076%
Pentamidine Isethionate (Antiprotozoan)	Pneumocystis Carinii Pneumonia (PCP) By Inhalation: Prevention of Pneumocystis Carinii Pneumonia (PCP) in high risk HIV patients	400%
Sodium Chloride 0.9% (Fluid)	Diluent for Inhaled and Injected Drugs Intravenous Replenishment Solution	1335%

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ABBOTT		
<u>DRUG</u>	<u>F.D.A. APPROVED INDICATIONS</u>	<u>THE FALSE PRICE SPREAD</u>
Tobramycin (Antibiotic)	Septicemia Lower Respiratory Tract Infection Central Nervous System Infections Intra-Abdominal Infections Skin and Skin Structure Infection Bone and Joint Infection Urinary Tract Infection	515%
Vancomycin (Antibiotic)	Serious or severe infections not treatable with other antimicrobials including: Resistant <i>Staphylococcal</i> Infections Resistant <i>Streptococcal</i> Infections <i>Diphtheroid</i> Endocarditis Pseudomembranous Colitis	1153%
Sterile Water for Injection (Fluid)	Reconstitution Solution for Injection Drugs	684%

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**PAGE 117 THROUGH PAGE 136
HAVE BEEN COMPLETELY REDACTED**

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[REDACTED]		
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]		
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

142. Each DEFENDANT was on notice that it was prohibited by federal statute, from paying, or causing the payment of, directly or indirectly, money or other financial benefit to induce its customers to order the specified drugs when the Medicare or States' Medicaid Programs would be paying claims. 42 U.S.C. §1320a-7b(b)(2).

143. Notwithstanding the DEFENDANTS' knowledge that the Government relied upon the DEFENDANTS' representations of price and cost and their knowledge of the applicable statutory requirements and prohibitions, each of the DEFENDANTS repeatedly, systematically and falsely reported inflated price and cost information, including but not limited to:

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a) Defendants ABBOTT, [REDACTED]

[REDACTED] repeatedly, systematically and falsely represented to the Medicare and States' Medicaid Programs that the prices of certain of the generic versions of the specified drugs were the same or higher than the published price for the equivalent brand drug when they knew that, in truth and in fact, the price of their generic drug was far less than the published price of the brand and that the States' Medicaid Programs and Medicare would pay and approve claims based upon their false representations of the price of their drugs, and

b) Defendants ABBOTT, [REDACTED]

[REDACTED]
[REDACTED] repeatedly, systematically and falsely represented to the Medicare and States' Medicaid Programs that the prices of certain of their specified drugs were increasing or remaining substantially constant when they knew that in truth and in fact the prices had fallen substantially or were otherwise priced far below the represented prices and the Medicare and States' Medicaid Programs would pay and approve claims based on their false representations of the price of their drugs.

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146.

[REDACTED]

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[REDACTED]					
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]					[REDACTED]
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147. [REDACTED]

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

















[REDACTED]


[REDACTED]


[REDACTED]

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148. The DEFENDANTS regularly make representations of false price and cost information directly to the Medicare Part B Carriers.

149. The DEFENDANTS also regularly make direct representations of false price and cost information directly to the various state Medicaid agencies that are relied upon in approving and paying claims.

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150. In many instances, the kickbacks paid from Governments' funds were in excess of 1,000% over the providers' true costs and over the reasonable reimbursement amounts which the Governments intended to pay. The grossly excessive profits have led to a proliferation of illegal split fee arrangements between the drug manufacturers' customers and persons or entities who are in a position to refer patients. The split fee/kickbacks also serve as a financial inducement for the referrals of more patients and greater utilization of the products.

151. The knowledge of the DEFENDANTS is further demonstrated by their systematic and ongoing, written and verbal communications with customers whereby they encourage and induce them to submit claims to Medicare and Medicaid to receive the excessive payments resulting from the DEFENDANTS' false price and cost representations.

152. As an example of the DEFENDANTS' use of their false and fraudulent practices to market their products follows:

■ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]
[REDACTED]
[REDACTED]

154. Patient Specific Examples Best Demonstrate the Huge Financial Inducements Created by the False Claim Schemes: The financial inducement to those in a position to increase the utilization of the DEFENDANTS' drugs is illustrated by the following examples of common drug therapies for certain of the specified drugs:

■ [REDACTED]
[REDACTED]
[REDACTED]

■ [REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED]

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[REDACTED]

Subsection 7e

**The Illegal Profit Spreads Are Often Enhanced By
Additional Unlawful Financial Inducements Such As
Free Goods, Direct Monetary Payments, Rebates, And
Agreements To Falsify Invoices**

155. The DEFENDANTS' false and misleading price and cost representations, as alleged above, create a profit spread between the cost of the drug to the provider and the reimbursement paid by Medicare and Medicaid. The amount of the financial inducement is thus paid from public funds under circumstances where paying or arranging such payments is expressly prohibited by law. The DEFENDANTS further act to increase the illegal profit spread, over and above that resulting from their false price and cost reports , through additional unlawful financial inducements such as:

a) Providing or arranging for the delivery of free goods in exchange for the purchase of the DEFENDANTS' specified drugs, the value of which is concealed from the Government, resulting in an additional spread between the true acquisition cost of the specified drugs and the false prices upon which Medicare and Medicaid reimburse.

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b) Making direct monetary payments to the provider ordering the drugs and concealing the true purpose of the payment by classifying it as a "marketing grant", "educational grant", "administrative fee", "research grant" or other name when the payment is, in truth, a financial inducement for ordering the drugs. These payments further reduce the providers' costs and are concealed from the Government.

c) Paying rebates to the providers which are concealed from the Government, further reducing the true cost of the drug and increasing the illegal profit spread.

d) Falsifying invoice prices to conceal additional reductions in the provider's true acquisition cost of the drugs.

156. Each of the methods employed by the DEFENDANTS in paying illegal financial inducements have the effect of misleading the Medicare and Medicaid Programs about the providers' cost of the drugs and of impeding the Programs' ability to estimate acquisition costs. The DEFENDANTS' actions result in claims being paid at exorbitant amounts.

Subsection 7f

**The DEFENDANTS Intentionally Impede Government Efforts
to Accurately Estimate Acquisition Costs and Deprive the Government of the
Benefits of Truthful Price and Cost Representations**

157. The DEFENDANTS have each knowingly and actively impeded the efforts of the Government: to arrive at reasonable estimates of acquisition cost in setting payment amounts for claims for the specified drugs; to benefit from drug price competition;

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and to use the Government's huge volume purchasing power for the benefit of the taxpayer. The DEFENDANTS' acts include the knowing reporting of inflated price and cost information alleged throughout this Amended Complaint and in many instances include additional acts and omissions such as those alleged in this Subsection.

158. [REDACTED]

159. [REDACTED]

160. [REDACTED]

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[REDACTED]

161.

[REDACTED]

162.

[REDACTED]

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163.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

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[REDACTED]

[REDACTED]					
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]					
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

164. Some state Medicaid programs have gone to exceptional lengths in their efforts to verify that drug manufacturers provide valid price and cost information for reimbursement purposes. By way of example, the Texas Medicaid authorities, during the time at issue in this Amended Complaint, required each of the DEFENDANTS to certify, in writing, the accuracy of their price and cost representations as a condition to their drugs being covered for reimbursement. The Relator's investigation has revealed that each of

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the DEFENDANTS, when responding to Texas, either affirmatively lied about their true prices, or omitted material information in order to mislead the Texas Medicaid officials.

165. The State of Texas required the DEFENDANTS to complete a specific form regarding the prices of their drugs. Immediately before the required signature by the DEFENDANTS' representatives is the following language:

"I hereby certify that the information submitted is correct to the best of my knowledge... I also agree to inform the Texas Department of Health of any changes in.....price....within fifteen (15) days of such change."

166. The State of Texas pays reimbursement for drugs covered by its Vendor Drug Program at the lesser of the provider's usual and customary charge or Estimated Acquisition Cost ("EAC"). In Texas' Pharmacy Provider Handbook, EAC is defined as either the Wholesale Estimated Acquisition Cost ("WEAC") or the Direct Estimated Acquisition Cost ("DEAC"). WEAC is the average price paid by providers purchasing a drug from a wholesaler. DEAC is the average price paid by a provider purchasing the drug directly for the drug's manufacturer.

167. Had the DEFENDANTS truthfully disclosed the price and cost information about the specified drugs, Texas Medicaid would have set reimbursement amounts for the specified drugs consistent with a reasonable estimation of acquisition cost. Because each of the DEFENDANTS having a duty to make truthful disclosures made false statements or omissions about the specified drugs, Texas Medicaid reimbursement has been paid at substantially greater amounts than intended by applicable law and Texas Medicaid policy.

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168. The Relator has provided the United States and Texas government authorities with sufficient information to identify the specific false statements and omissions of each DEFENDANT. A representative example is that of DEFENDANT ABBOTT'S false statements for the price of its injectable drug Furosemide made in its written certification of drug prices to Texas Medicaid. ABBOTT knowingly and falsely represented to Texas Medicaid that the price to wholesalers and direct to pharmacies of Furosemide, NDC No. 00074-6054-02, was \$82.75 for twenty five of the 10 mg/2ml vials when ABBOTT knew that its true price was \$27.48 and substantially less than \$81.75. The Relator was, at all times from June 1, 1994 through May 31, 1997, able to purchase ABBOTT's Furosemide, NDC No: 00074-6054-02, for only \$27.48 through a group purchasing organization.

169. The United States Congress has attempted to assist the States' Medicaid programs in limiting reimbursement amounts for prescription drugs to a reasonable estimate of acquisition cost, by empowering the Health Care Financing Administration to set a "Federal Upper Limit" ("FUL") for drugs paid for by Medicaid. HCFA has not established a FUL for most of the infusion, injectable and biological drugs at issue in this case. However, some of the DEFENDANTS have expanded the false claims scheme to certain oral prescription drugs for which an FUL has been set. These oral drugs are dispensed by retail pharmacies and the creation of a spread may financially induce the pharmacy to dispense the generic version with the greatest profit spread between acquisition cost and the FUL. False inflated price reports cause the FUL to be set at a

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higher amount than would be the case if the DEFENDANT provided truthful prices. The Government attempt to limit amounts paid for claims is thus circumvented.

170. HCFA's description of the FUL program in its current web site states the applicable government claims policy :

"In 1987, regulations limited the amount which Medicaid could reimburse for drugs with available generic drugs under the federal upper limit program. These limits are intended to assure that the Federal government acts as a prudent buyer of drugs. The concept of the upper limits program is to achieve savings by taking advantage of the current market prices. Until the passage of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), the Federal Upper Limit (FUL) could be established only if all generic versions of a drug product had been classified as therapeutically equivalent (A-rate) by the FDA in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations" and at least three suppliers were listed in the current editions of published national compendia. OBRA '90 expanded that criteria and permitted the establishment of a FUL for a drug product if there are three (or more) generic versions of the product rated therapeutically equivalent (A-rated) regardless of the ratings of other versions (B-rated) and at least three suppliers are listed in the current editions of published national compendia."

171. A representative example of the DEFENDANTS' efforts to deprive the Government of the benefit of the Federal Upper Limit involves the drug [REDACTED]. [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

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[REDACTED]

[REDACTED]

172. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

173. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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174. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

175. [REDACTED]

[REDACTED]

176. The DEFENDANTS' continued exploitation of false claim scheme to impede Government efforts to estimate costs is evidenced by pricing representations made for the generic injectable drug [REDACTED]. The Brand name for [REDACTED] manufactured by [REDACTED] reported 1996 sales of \$529,300,000.00 for [REDACTED]. On April 22, 1997 [REDACTED] patent expired. [REDACTED] is [REDACTED] drug that is widely prescribed to persons who are suffering with the HIV disease. Prior to the patent expiration, VAC's wholesale cost for 1 gm of [REDACTED] was \$103.67 and its AWP was \$113.20 (a difference of 9%). Defendant ABBOTT was one of the first companies to announce distribution of a generic injectable Acyclovir. On or about February 19, 1997, Defendant ABBOTT set a true pre distribution price of \$70.00 for 1 gm which was approximately 30% less than [REDACTED] brand [REDACTED]. However

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ABBOTT fraudulently and falsely reported to Medical Economics and First Data Bank a Direct Price of \$160.00 for 1 gm which caused Medical Economics and First Data Bank to set a false and fraudulent AWP of \$190.00 for 1 gm or approximately 70% more than the Brand. Before ABBOTT could begin distribution of its generic injectable Acyclovir, another drug manufacturer announced distribution of a competing generic injectable Acyclovir at an initial price less than ABBOTT's. On or about April 28, 1997, ABBOTT reacted to the market conditions of price competition by lowering its true price to providers from \$70.00 to \$60.00 for 1 gm. Despite ABBOTT's reduction in prices to providers, ABBOTT continued to publish its original grossly inflated false and fraudulent representations of cost and price. During a telephone conversation between VAC's Bentley and an ABBOTT marketing/sales representative, on or about May 30, 1997, Bentley was informed that ABBOTT was committed to capturing market share by "widening the spread for providers" by lowering the true price while inflating the price represented to Medicare and Medicaid. The following charts contain the specific allegations demonstrating the Acyclovir fraud:

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BRAND

COMPANY	DRUG	NDC	RED BOOK AWP	VEN-A-CARE COST	FLORIDA MEDICAID
[REDACTED]	[REDACTED]	[REDACTED]	\$ 56.60	\$ 47.20	\$ 50.47083
[REDACTED]	[REDACTED]	[REDACTED]	\$113.20	\$103.67	\$100.94059

VERSUS

GENERIC

COMPANY	DRUG	NDC	RED BOOK "AWP"	RED BOOK "DP"	VEN-A- CARE COST	FLORIDA MEDICAID
Abbott	Acyclovir Sodium 500 mg	00074-4427-01	\$95.00	\$80.00	\$35.00 \$30.00	\$ 84.5500
Abbott	Acyclovir Sodium 1,000 mg (1 gm)	00074-4452-01	\$190.00	\$160.00	\$70.00 \$60.00	\$169.1000

177. The DEFENDANTS' actions have also, in many instances, deprived the Government of the full benefit of the Medicaid rebate program mandated by the Omnibus Budget Reconciliation Act of 1990 ("OBRA '90"). OBRA 90 was implemented after numerous Congressional hearings. Congress concluded that the Medicaid Program, as the largest single purchaser of prescription drugs in the United States should be entitled to the same discounts that were routinely given by the drug manufacturers to large purchasers (See Skyrocketing Drug Prices: Hearings Before the Special Committee on Aging, United

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States Senate, 101st Congress, 290-297 (1989). As a result, Congress, in the Omnibus Budget Reconciliation Act of 1990 ("OBRA '90"), established the Medicaid Rebate Program PL-101-508, 104 Stat. 1388 (1990) to give the State Medicaid Programs the "benefit of the best price (emphasis added) for which a manufacturer [sold] a prescription drug to any....private purchaser." H.R. Rep. No. 101-881, at 96 (1990). The Rebate Program requires all manufacturers, as a condition to their drugs being paid for (covered) by Medicaid, to enter into a Rebate Agreement with the Secretary of the Department of Health and Human Services and pay a rebate amount to each State on a quarterly basis based on the following formula:

a) Basic rebate for single source drugs and innovator multiple source drugs (Brand drugs) shall be equal to the product of-

(i) the total number of units

(ii) the difference between the average manufacturer price and the best price with minimum rebate percentages ranging from 12.5% (12/31/1990-09/30/1992) to 15.1% after December 31, 1995.

b) Basic rebate other drugs (generic drugs) shall be equal to the product of-

(i) the total number of units

(ii) the average manufacturer price

(iii) 10% (before January 1, 1994)

(iv) 11% (after December 31, 1993)

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Best price ("BP") is generally defined as the lowest price (inclusive of cash discounts, free goods volume discounts etc.) available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, etc excluding direct government purchases.

178. Average manufacturer price ("AMP") is generally defined as the average price paid to the manufacturer during the rebate period by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts. Manufacturers report their BP and AMP to HCFA on a quarterly basis. HCFA, in turn, calculates the rebate amount either AMP minus BP (or the 15.1% minimum) for Brand drugs or AMP multiplied by 11% for generic drugs and forwards the figures by NDC number to the States. The States multiply the rebate amount by the number of units that the State paid for during the quarter to determine the rebate amount due and submit the requested amount to the manufacturer. The manufacturers remit this payment on a quarterly basis, withholding any disputed amount.

179. The DEFENDANTS have each participated in the Medicaid Rebate Program and as such were required to calculate their drugs BP and/or AMP. The DEFENDANTS have additionally calculated other various representations of prices such as AWP, WAC, DP and list prices that are the industry benchmarks used for establishing reimbursements for the Medicare and Medicaid Programs. The DEFENDANTS reported their representations of prices such as AWP, WAC, DP and list prices to First Data Bank and Red Book with the knowledge that First Data Bank and Red Book were providing the

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DEFENDANTS representations to the State Medicaid Programs and the Medicare Carriers for the purpose of establishing Medicaid and Medicare reimbursements.

180. WAC is defined as wholesaler acquisition cost. AMP is defined as the average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts. Therefore if a manufacturer honestly reports its AMP and WAC they should be very close to, if not the same, amount. However, for Medicaid and Medicare reimbursement purposes the DEFENDANTS have in many instances falsely and fraudulently represented inflated (or caused to be inflated) AWP's and WAC's that are in some cases more than 500% over their AMP's, thus causing the States' Medicaid Programs after rebate net cost to be many times greater than the DEFENDANTS' Best Price. The false pricing scheme by the DEFENDANTS has fraudulently thwarted the Congressional intent of providing the States with the benefit of the DEFENDANTS' best prices. The following Subparagraphs a through d provide examples of how the false price representations of DEFENDANTS ABBOTT, [REDACTED] have caused Medicaid reimbursement to be based on WAC's that substantially exceed AMP's used for Medicaid rebate purposes. As a result, the State's Medicaid programs have been deprived of the substantial fiscal benefits intended and required by the Medicaid Rebate Statute:

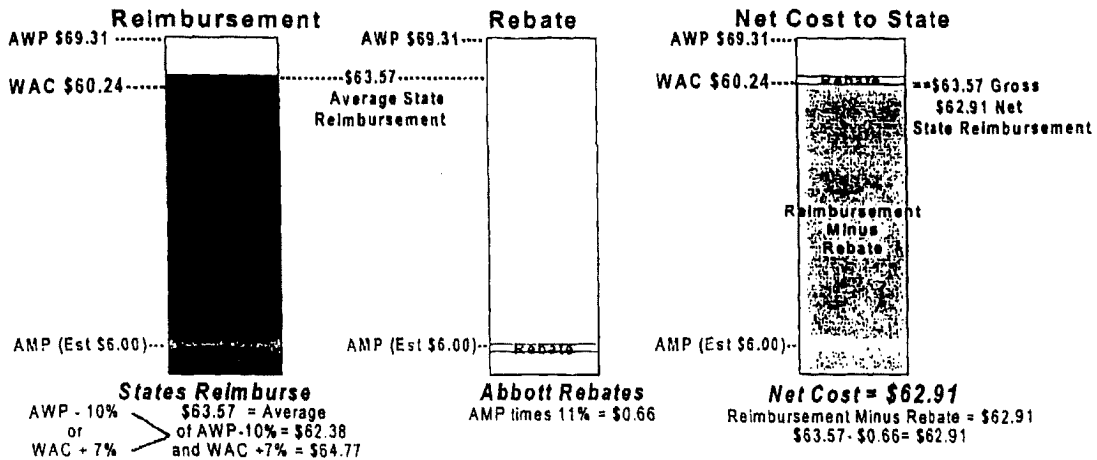
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a.) Abbott's false prices affect Medicaid Rebate calculation.**EXAMPLE 1 ABBOTT'S FALSE AND FRAUDULENT STATEMENTS****Abbott's Vancomycin HCL**

NDC # 00074-6533-01, 1998 "AWP" = \$69.31 1998 "WAC" = \$60.24

1998 REBATE AMOUNT = \$0.66 ea.

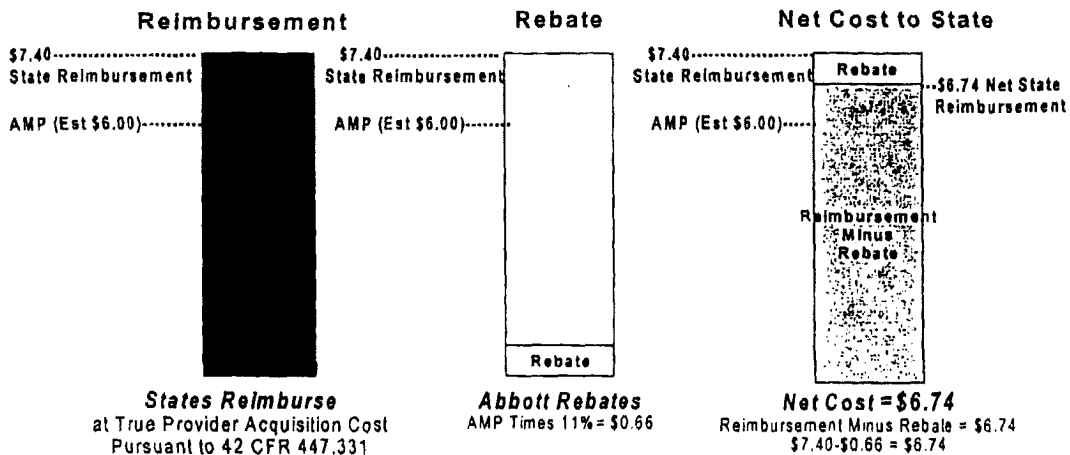
In this example, the States reimburse at the false and fraudulent prices represented by Abbott, either through AWP minus a percentage or WAC plus a percentage.

• **EXAMPLE 2****IF STATES USED TRUE PRICES****Abbott's Vancomycin HCL**

NDC # 00074-6533-01, 1998 WHOLESale PRICE = \$7.40 (Florida Infusion)

1998 REBATE AMOUNT = \$0.66 ea.

In this example, the States reimburse at a truthful estimated acquisition cost as illustrated by Florida Infusion prices, pursuant to 42 CFR 447.331.



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**PAGES 171 THROUGH 173
HAVE BEEN COMPLETELY REDACTED**

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181. Drug manufacturers who wish to sell their products to the Federal Government healthcare providers such as the Department of Defense Hospitals and the Veterans Administration, are required by law to sell at or below their lowest prices to their best commercial customers. The law is implemented through the Federal Supply Schedule ("FSS"). The DEFENDANTS' representations about their lowest prices are included on the FSS for each of the drugs.

182. The DEFENDANTS' prices to some customers, after reduction for concealed financial inducements, resulted in true prices that were below the prices reported for inclusion on the FSS resulting in a false FSS price. This caused the Government to pay FSS based claims at inflated amounts. Accordingly, the DEFENDANTS who reported false FSS prices are liable for additional false claims damages in the amount by which their FSS price representations exceeded their true prices .

183. For many of the specified drugs, the DEFENDANTS' false representations of price and cost caused the Medicare Program to pay and approve claims at such exorbitant amounts that the 20% co-payment paid by the patient exceeded the true price of the drugs. A representative example is alleged in Table No. 5 below lists some of the specified drugs, the amount approved in 1996 by Florida Medicare, the 20% co-payment paid by the patient, and the true price paid by the Relator:

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TABLE NO. 5

**DRUGS WHERE THE MEDICARE PROGRAM'S
20% CO-PAYMENT
EXCEEDS THE TOTAL PRICE OF THE DRUG**

Drug	HCPCS Code	1996 Florida Medicare Allowable	20% Co-Payment	1996 Relator's Cost
Leucovorin 50 mg	J0640	\$ 21.53	\$ 4.36	\$ 1.89
[REDACTED]	[REDACTED]	\$ 3.05	\$ 0.61	\$ 0.22
[REDACTED]	[REDACTED]	\$ 8.56	\$ 1.72	\$ 0.79
Sodium Chloride 0.9% 1000 ml	J7030	\$ 11.06	\$ 2.21	\$ 0.95
Sodium Chloride 0.9% 500 ml	J7040	\$ 10.14	\$ 2.03	\$ 0.79
5% Dextrose/ Sodium Chloride 0.9% 500 ml	J7042	\$ 10.24	\$ 2.05	\$ 0.78
Sodium Chloride 0.9% 250 ml	J7050	\$ 9.43	\$ 1.89	\$ 0.78
5% Dextrose in Water 500 ml	J7060	\$ 9.98	\$ 1.99	\$ 0.75
5% Dextrose in Water 1000 ml	J7070	\$ 11.23	\$ 2.25	\$ 0.95
Lactated Ringers 1000 ml	J7120	\$ 12.43	\$ 2.48	\$ 1.02
[REDACTED]	[REDACTED]	\$ 1.37	\$ 0.27	\$ 0.26
[REDACTED]	[REDACTED]	\$ 1.23	\$ 0.25	\$ 0.10

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Drug	HCPSC Code	1996 Florida Medicare Allowable	20% Co-Payment	1996 Relator's Cost
[REDACTED]	[REDACTED]	\$ 1.23	\$ 0.25	\$ 0.10
[REDACTED]	[REDACTED]	\$ 45.08	\$ 9.02	\$ 9.00
[REDACTED]	[REDACTED]	\$225.40	\$45.08	\$45.00
[REDACTED]	[REDACTED]	\$ 51.43	\$10.29	\$10.00
[REDACTED]	[REDACTED]	\$102.89	\$20.58	\$20.00
Etoposide 10 mg	J9181	\$ 14.20	\$ 2.84	\$ 1.65
Etoposide 100 mg	J9182	\$141.97	\$28.35	\$16.50
[REDACTED]	[REDACTED]	\$ 40.04	\$ 8.01	\$ 6.85
[REDACTED]	[REDACTED]	\$ 31.75	\$ 6.35	\$ 3.75
[REDACTED]	[REDACTED]	\$ 38.25	\$ 7.65	\$ 7.27

184. In many cases the DEFENDANTS' false claims scheme have caused the Government to pay claims for generic equivalents of the specified drugs in amounts greater than the brand name version of the drug and the DEFENDANTS have thus deprived the Government of the expected savings arising from utilization of generics. The following Table 6 contains some examples of this significant impact of the DEFENDANTS' false claim scheme:

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TABLE NO. 6

THE MEDICARE AND MEDICAID PROGRAMS
 DUPED INTO PAYING AS MUCH OR MORE
 FOR GENERIC DRUGS THAN THEIR EQUIVALENT BRAND

[REDACTED]				
[REDACTED]				
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]				
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

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[REDACTED]				
[REDACTED]				
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]				
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

DRUG: VANCOMYCIN, HCPCS J3370				
BRAND: VANCOCIN				
COMPANY	SIZE	NDC #	AWP 1996 Red Book	RELATOR'S COST
[REDACTED]	500 mg	[REDACTED]	\$7.80	\$6.50
[REDACTED]	1 gm	[REDACTED]	\$15.61	\$14.13

GENERIC: VANCOMYCIN				
COMPANY	SIZE	NDC #	AWP 1996 Red Book	RELATOR'S COST
Abbott	500 mg	00074-4332-01	\$31.44	\$3.51
Abbott	1 gm	00074-6533-01	\$62.86	\$7.01

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DRUG: PENTAMIDINE				
BRAND: PENTAM 300				
COMPANY	SIZE	NDC #	AWP 1996 Red Book	RELATOR'S COST
████████	300 mg	████████	\$98.75	\$49.00

GENERIC: PENTAMIDINE				
COMPANY	SIZE	NDC #	AWP 1996 Red Book	RELATOR'S COST
Abbott	300 mg	00074-4548-01	\$113.54	\$43.00

DRUG: TOBRAMYCIN SULFATE, HCPCS J3260				
BRAND: NEBCIN				
COMPANY	SIZE	NDC #	AWP 1996 Red Book	RELATOR'S COST
████	40 mg/ml 80 mg	████████	\$7.28	\$6.07

GENERIC: TOBRAMYCIN SULFATE				
COMPANY	SIZE	NDC #	AWP 1996 Red Book	RELATOR'S COST
Abbott	40 mg/ml 80 mg	00074-3578-01	\$9.83	\$3.63

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DRUG: AMIKACIN SULFATE				
BRAND: AMIKIN				
COMPANY	SIZE	NDC #	AWP 1996 Red Book	RELATOR'S COST
██████████	250 mg/ml 2 ml	██████████	\$46.99	\$13.25




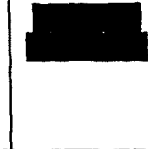












































GENERIC: AMIKACIN SULFATE				
COMPANY	SIZE	NDC #	AWP 1996 Red Book	RELATOR'S COST
Abbott	250 mg/ml 2 ml	00074-1956-01	\$99.25	\$12.00
██████████	500 mg/ml 2 ml	██████████	\$63.75	\$14.00

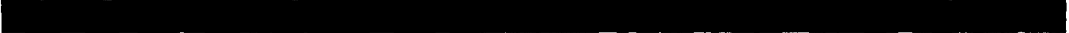
185. The DEFENDANTS' false claims scheme has also deprived the Government of the benefits of normal price competition causing it in some cases to pay thousands of percent above the price that would be set by normal market forces, but for the DEFENDANTS' false price and cost representations.

186. The Government and its health program beneficiaries are damaged when the DEFENDANTS create a financial inducement for providers to order patented drugs by continually increasing the spread over time. This is the case with DEFENDANTS' ██████████
██████████ as exhibited by the following Table No. 7.

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TABLE NO. 7

187. The DEFENDANTS also deprive the Government of the benefits of price competition when generic versions of a drug become available and compete with the "brand". 





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TABLE NO. 8

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

188. The actions of the DEFENDANTS alleged herein result in grossly excessive amounts being paid to their customers by the Medicare and States' Medicaid Programs for claims submitted for the specified drugs. The exorbitant payments induce physicians, clinics and specialty pharmacies to increase utilization of the specified drugs. The financial inducement was so great for many of the specified pharmaceuticals at issue in this Third Amended Complaint that the profits derived from the provision of the specified drugs greatly exceeded the physicians' professional fees and provided what can only be characterized as "windfall profits." In many markets, including the Relator's, specialty pharmacies and clinics are often unable to compete unless they enter financial arrangements with prescribing physicians whereby the grossly excessive amounts paid by the Medicare and States' Medicaid Programs are split with the prescribing physicians. Over the last six (6) years, the Relator's business has all but been extinguished because of the Relator's refusal

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to benefit from the false and fraudulent claims schemes specified herein. The Relator has been unable to effectively compete with those physicians, clinics and specialty pharmacies who benefit from the DEFENDANTS' false claims scheme because the financial inducement to the prescribing physicians often exceeds their compensation from the practice of medicine.

SECTION NO. 8

**THE SPECIFIC FALSE PRICE AND COST
REPRESENTATIONS OF DEFENDANT
ABBOTT**

189. At various times from on or after June 23, 1989 and continuing through the present date, Defendant ABBOTT knowingly caused the Medicare program and the States' Medicaid programs throughout the United States and its territories to pay false or fraudulent claims for drugs specified in this Section and further made or used false or fraudulent records and/or statements to get such claims paid or approved. As a result of the said actions of Defendant ABBOTT and those persons and entities acting directly or indirectly in concert with Defendant ABBOTT the Medicare and States' Medicaid Programs paid grossly excessive, unreasonable and unlawful amounts for claims for the drugs specified in this Section. The acts committed by Defendant ABBOTT that caused the Medicare and States' Medicaid Programs to pay or approve said false or fraudulent claims included, but were not necessarily limited to, knowingly making false or fraudulent representations about prices and costs of the drugs specified in this Section which Defendant ABBOTT knew or should have known would be relied upon by the Medicare and States' Medicaid Programs

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in paying or approving claims for the drugs specified in this Section. Each of said representations were material and were relied upon by the Medicare and States' Medicaid Programs in paying or approving claims for the drugs specified in this Section.

190. Defendant ABBOTT knowingly caused its false or fraudulent price and cost representations to be published in the years specified in this Section in the Red Book, the Blue Book and the First Data Bank's Automated Services and further made or used false records or statements regarding its prices and costs of the drugs specified in this Section and submitted same to the Medicare and States' Medicaid Programs continuously throughout the years specified in this Section. For the purposes of specificity and particularity, the said false price and cost representations as they were reflected in the Red Book and Blue Book have been organized into a chart form for each drug in question and for each NDC Number assigned to each drug in question. The information provided under the columns for Defendant's Published Price, and Red Book and Blue Book "AWP" and "DP" reflects the false price and cost representations made by the Defendant ABBOTT. The information under the Relator's Cost columns reflects the true price that Defendant ABBOTT charged the Relator for the drug or caused another entity to charge the Relator for the drug. As a very small infusion pharmacy, the Relator does not always receive the lowest prices available to volume purchasers. Accordingly, a comparison of the Relator's costs with the price and cost representations made by the Defendant ABBOTT establishes the falsity of ABBOTT's representations for the drugs and years specified as follows:

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a. DRUG: SODIUM CHLORIDE 0.9%
250 ML

MEDICAID

NDC NO.: 00074-7983-02

MEDICARE

HCPCS J7050

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK		BLUE BOOK		RELATOR'S WHOLESALE COST	RELATOR'S DIRECT COST
		"AWP"	"DP"	"AWP"	"DP"		
1993	\$7.59	\$8.59		\$8.59	\$7.23	\$1.50	\$1.07
1994	\$7.82	\$9.01		\$9.01	\$7.59	\$1.33	\$0.95
1995	\$8.05	\$9.29		\$9.29	\$7.82	\$1.33	\$0.95
1996		\$9.56		\$9.56	\$8.05	\$1.33	\$0.95
1997		\$10.03				\$1.33	\$0.95

Defendant, ABBOTT caused the payment or approval of false or fraudulent claims during the years specified in the above chart by the Medicare and/or States' Medicaid Programs for the following additional size(s) of Sodium Chloride:

SIZE	MEDICAID NDC#	MEDICARE HCPCS
50 ml	00074-7101-13	-----
100 ml	00074-7101-23	-----
500 ml	00074-7983-03	J7040
1,000 ml	00074-7983-09	J7030

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b. DRUG: 5% DEXTROSE IN WATER
500 MLMEDICAID
NDC NO.: 00074-7922-03MEDICARE
HCPCS J7060

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK		BLUE BOOK		RELATOR'S WHOLESALE COST	RELATOR'S DIRECT COST
		"AWP"	"DP"	"AWP"	"DP"		
1993	\$7.71	\$8.72		\$8.72	\$7.34	\$1.80	\$0.97
1994	\$7.94	\$9.16		\$9.16	\$7.71	\$1.50	\$0.96
1995	\$8.18	\$9.43		\$9.43	\$7.94	\$1.50	\$0.96
1996		\$9.71		\$9.71	\$8.18	\$1.50	\$0.96
1997		\$10.20				\$1.50	\$0.96

Defendant, ABBOTT caused the payment or approval of false or fraudulent claims during the years specified in the above chart by the Medicare and/or States' Medicaid Programs for the following additional size(s) of 5% Dextrose in Water:

SIZE	MEDICAID NDC#	MEDICARE HCPCS
50 ml	00074-7100-13	-----
100 ml	00074-7100-23	-----
250 ml	00074-7100-02	-----
1,000 ml	00074-7922-09	J7070

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c. DRUG: DEXTROSE 5% WITH SODIUM CHLORIDE 0.9%
500 ML

MEDICAID

NDC NO.: 00074-7941-03

MEDICARE

HCPCS J7042

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK		BLUE BOOK		RELATOR'S WHOLESALE COST	RELATOR'S DIRECT COST
		"AWP"	"DP"	"AWP"	"DP"		
1993	\$8.28	\$9.37		\$9.37	\$7.89	\$1.15	\$1.04
1994	\$8.53	\$9.83		\$9.83	\$8.28	\$1.15	\$1.03
1995	\$8.79	\$10.13		\$10.13	\$8.53	\$1.15	\$1.03
1996		\$10.44		\$10.44	\$8.79	\$1.15	\$1.03
1997		\$10.96				\$1.15	\$1.03

Defendant, ABBOTT caused the payment or approval of false or fraudulent claims during the years specified in the above chart by the Medicare and/or States' Medicaid Programs for the following additional size(s) of Dextrose 5% with Sodium Chloride 0.9%:

SIZE	MEDICAID NDC#	MEDICARE HCPCS
250 ml	00074-7941-02	-----
1,000 ml	00074-7941-09	-----

d. DRUG: RINGERS LACTATE
1,000 ML

MEDICAID

NDC NO.: 00074-7953-09

MEDICARE

HCPCS J7120

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK		BLUE BOOK		RELATOR'S WHOLESALE COST	RELATOR'S DIRECT COST
		"AWP"	"DP"	"AWP"	"DP"		
1993	\$10.30			\$11.64	\$9.81	\$1.36	\$1.30
1994	\$10.61	\$12.23		\$12.23	\$10.30	\$1.36	\$1.14
1995	\$10.93	\$12.60		\$12.59	\$10.61	\$1.36	\$1.14
1996		\$12.98		\$12.97	\$10.93	\$1.36	\$1.14
1997		\$13.63				\$1.36	\$1.14

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Defendant, ABBOTT caused the payment or approval of false or fraudulent claims during the years specified in the above chart by the Medicare and/or States' Medicaid Programs for the following additional size(s) of Ringers Lactate:

SIZE	MEDICAID NDC#	MEDICARE HCPCS
250 ml	00074-7953-02	-----
500 ml	00074-7953-03	-----

e. DRUG: VANCOMYCIN HCL
500 MG

MEDICAID
NDC NO.: 00074-4332-01

MEDICARE
HCPCS J3370

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK		BLUE BOOK		RELATOR'S WHOLESALE COST	RELATOR'S DIRECT COST
		"AWP"	"DP"	"AWP"	"DP"		
1993	\$24.72	\$27.95		\$27.95	\$23.54		\$3.76
1994	\$25.46	\$29.35		\$29.36	\$24.72		\$3.51
1995	\$26.48	\$30.23		\$29.36	\$24.72	\$4.20	\$3.51
1996		\$31.44				\$3.95	\$3.51
1997						\$3.75	\$3.51

Defendant, ABBOTT caused the payment or approval of false or fraudulent claims during the years specified in the above chart by the Medicare and/or States' Medicaid Programs for the following additional size(s) of Vancomycin HCL:

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SIZE	MEDICAID NDC#	MEDICARE HCPCS
500 mg Advantage	00074-6535-01	-----
1 gm	00074-6533-01	-----
5.0 gm	00074-6509-01	-----

f. DRUG: TOBRAMYCIN SULFATE
80 MG

MEDICAID
NDC NO.:00074-3578-01

MEDICARE
HCPCS J3260

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK		BLUE BOOK		RELATOR'S WHOLESALE COST	RELATOR'S DIRECT COST
		"AWP"	"DP"	"AWP"	"DP"		
1993		\$8.74		\$8.74	\$7.36	\$4.92	
1994		\$9.18		\$9.18	\$7.73	\$4.92	\$3.63
1995		\$9.45		\$9.45	\$7.96	\$4.92	\$3.63
1996		\$9.83		\$9.83	\$8.28	\$4.92	\$3.63
1997		\$10.32				\$4.92	\$3.63

Defendant, ABBOTT caused the payment or approval of false or fraudulent claims during the years specified in the above chart by the Medicare and/or States' Medicaid Programs for the following additional size(s) of Tobramycin Sulfate:

SIZE	MEDICAID NDC#	MEDICARE HCPCS
20 mg	00074-3577-01	-----
60 mg	00074-3582-01	-----
60 mg	00074-3469-13	-----
60 mg	00074-3254-03	-----
80 mg	00074-3255-03	-----

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SIZE	MEDICAID NDC#	MEDICARE HCPCS
80 mg	00074-3470-23	-----
80 mg	00074-3583-01	-----
2,000 mg	00074-3590-02	-----

g. DRUG: PENTAMIDINE ISETHIONATE
300 MGMEDICAID
NDC NO.: 00074-4548-01MEDICARE
HCPCS

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK		BLUE BOOK		RELATOR'S WHOLESALE COST	RELATOR'S DIRECT COST
		"AWP"	"DP"	"AWP"	"DP"		
1993	\$89.25	\$85.00		\$100.94	\$85.00	\$75.00	
1994	\$91.93	\$105.98		\$105.98	\$89.25		
1995	\$95.61	\$109.17		\$109.17	\$91.93	\$59.00	\$43.00
1996		\$113.54		\$113.54	\$95.61		\$43.00
1997		\$119.21					

h. DRUG: CLINDAMYCIN PHOSPHATE
900 MGMEDICAID
NDC NO.: 00074-4052-01

MEDICARE

YEAR	DEFENDANT'S PUBLISHED PRICE	RED BOOK		BLUE BOOK		RELATOR'S WHOLESALE COST	RELATOR'S DIRECT COST
		"AWP"	"DP"	"AWP"	"DP"		
1993	\$20.62	\$23.32		\$23.32	\$19.64	\$3.25	\$7.25
1994	\$21.24	\$24.49		\$24.49	\$20.62	\$3.25	\$3.20
1995	\$22.09	\$25.22		\$25.22	\$21.24	\$3.25	\$3.20
1996		\$26.23		\$26.23	\$22.09	\$3.25	\$3.20
1997		\$27.54				\$3.25	\$3.20

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**PAGES 192 THROUGH 298
HAVE BEEN COMPLETELY REDACTED
WHICH INCLUDES THE END OF
PARAGRAPH 191 THROUGH
PARAGRAPH 238**

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SIZE	MEDICAID NDC#	MEDICARE HCPCS
██████	██████████████	██████
██████	██████████████	██████
██████	██████████████	██████
██████	██████████████	██████
██████████	██████████████	██████
██████	██████████████	██████
██████	██████████████	██████
██████	██████████████	██████
██████	██████████████	██████
██████	██████████████	██████
██████████	██████████████	██████
██████	██████████████	██████

As a direct and proximate result of the actions of the Defendant [REDACTED] alleged herein, the United States has sustained damages recoverable under the False Claims Act, together with triple damages, penalties, attorneys' fees and costs.

COUNT 1

**FALSE CLAIMS ACT;
CAUSING PRESENTATION OF FALSE OR FRAUDULENT CLAIMS**

239. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES and on behalf of the Relator, against the Defendants: ABBOTT LABORATORIES, INC.; [REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED], under the False

Claims Act, 31 U.S.C. §§3729-3732.

240. Relator realleges and incorporates by reference paragraphs 1 through 238 as if fully set forth herein and further alleges as follows:

241. The DEFENDANTS from a date on or before June 23, 1989 to the present date, knowingly [as defined in 31 USC, §3729(b)] caused to be presented to officers or employees of the UNITED STATES GOVERNMENT and STATE GOVERNMENTS false or fraudulent claims [as explained in United States v. Neifert-White, 390 US 228, 232-233 (1968)] for payment or approval, in that the DEFENDANTS caused to be presented to officers or employees of the UNITED STATES GOVERNMENT and STATE GOVERNMENTS false or fraudulent price and cost information for the drugs specified

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herein and caused the UNITED STATES and STATE GOVERNMENTS to pay out sums of money to the providers and suppliers of the DEFENDANTS' specified drugs, grossly in excess of the amounts permitted by law, resulting in great financial loss to the UNITED STATES and STATE GOVERNMENTS.

242. Because of the DEFENDANT PHARMACEUTICAL MANUFACTURERS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of One Billion Dollars (\$1,000,000,000.00), all in violation of **31 U.S.C. §3729(a)(1)**

COUNT II

**FALSE CLAIMS ACT; CAUSING A FALSE RECORD OR STATEMENT
TO BE MADE OR USED TO GET A FALSE OR FRAUDULENT
CLAIM PAID OR APPROVED BY THE GOVERNMENT**

243. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES and on behalf of the Relator, against the Defendants: ABBOTT LABORATORIES, INC.; [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED], under the False Claims Act, 31 U.S.C. §§3729-3732.

244. Relator realleges and incorporates by reference paragraphs 1 through 238 as if fully set forth herein and further alleges as follows:

245. The DEFENDANTS, from a date on or before June 23, 1989 to the present date, knowingly [as defined in §3729(b)] caused false records or statements to be made or used to get false or fraudulent claims [as explained in United States v. Neifert-White, 390 US 228, 232-233 (1968)] to be paid or approved by the GOVERNMENT, in that the DEFENDANTS, caused false records or statements of prices and costs of the DEFENDANTS' drugs specified herein to be used by the GOVERNMENT to pay or approve claims presented by the providers and suppliers of the DEFENDANTS' specified drugs, which claims were grossly in excess of the amounts permitted by law, resulting in great financial loss to the UNITED STATES and STATE GOVERNMENTS.

246. Because of the DEFENDANTS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of One Billion Dollars (\$1,000,000,000.00), all in violation of 31 U.S.C. §3729(a)(2).

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COUNT III

**FALSE CLAIMS ACT; CAUSING FALSE RECORDS OR
STATEMENTS TO BE USED TO CONCEAL AN OBLIGATION
TO PAY MONEY TO THE GOVERNMENT**

247. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES and on behalf of the Relator, against the Defendants: ABBOTT LABORATORIES, INC.; [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED], under the False Claims Act, 31 U.S.C. §§3729-3732.

248. Relator realleges and incorporates by reference paragraphs 1 through 238 as if fully set forth herein and further alleges as follows:

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249. The DEFENDANTS, from a date on or before June 23, 1989 to the present date, knowingly [as defined in §3729(b)] caused false records or statements to be made or used to conceal obligations to pay money to the GOVERNMENT, in that: the DEFENDANTS knew that the UNITED STATES' Medicare Program and the States' Medicaid Programs were using the DEFENDANTS' false price and cost representations for purposes of paying or approving claims of the providers and suppliers of the DEFENDANTS' specified drugs; the DEFENDANTS knew that sums of money paid by the UNITED STATES and States' Governments to the providers and suppliers of the DEFENDANTS' specified drugs were grossly in excess of the amounts permitted by law; the DEFENDANTS knew it was the obligation of the UNITED STATES Medicare Part B carriers and State Governments to recoup governments' funds paid in excess of the amounts permitted by law; the DEFENDANTS, nevertheless, continued to cause the using and making of false records or statements of prices and costs for the specified drugs that were grossly in excess of the reasonable amounts permitted by law; and the DEFENDANTS thus concealed from the UNITED STATES Medicare Part B carriers and State Governments an obligation of the providers and suppliers of the DEFENDANTS' specified drugs to pay recoupment monies to the UNITED STATES and State Governments, resulting in great financial loss to the UNITED STATES and State Governments.

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250. Because of the DEFENDANTS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of One Billion Dollars (\$1,000,000,000.00), all in violation of 31 U.S.C. §3729(a)(7).

COUNT IV

**FALSE CLAIMS ACT; CAUSING PRESENTATION OF
FALSE OR FRAUDULENT CLAIMS; ILLEGAL REMUNERATION**

251. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES and on behalf of the Relator, against the Defendants: ABBOTT LABORATORIES, INC.; [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED], under the False Claims Act, 31 U.S.C. §§3729-3732.

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252. Relator realleges and incorporates by reference paragraphs 1 through 238 as if fully set forth herein and further alleges as follows:

253. The DEFENDANTS, from on or about June 23, 1989 to the present date, knew that the prices charged to their customers for the specified drugs were significantly reduced in amount from the prices and costs represented by the DEFENDANTS and upon which the DEFENDANTS knew Medicare and Medicaid claims would be approved and paid. Accordingly, the DEFENDANTS have each knowingly offered or paid, or caused to be offered or paid, directly or indirectly, overtly or covertly, in cash or in kind, remuneration to their customers in the form of price reductions and/or in the form of illegal remuneration from the Medicare and/or States' Medicaid Programs to induce them to purchase, order or arrange or to recommend purchasing, arranging or ordering the specified drugs for which the DEFENDANTS knew that payment would be made, in whole or in part, by the Medicare and States' Medicaid Programs. Such financial inducement is specifically prohibited by 42 U.S.C. §1320a-7b(b)(2) and 18 U.S.C §2.

254. The DEFENDANTS knew that the Medicare and States' Medicaid Programs would not pay or approve claims for the specified drugs if it were disclosed to the Medicare and States' Medicaid Programs that said claims were for amounts that included remuneration prohibited by 42 U.S.C. §1320a-7b(b)(2).

255. The DEFENDANTS also knew that their customers, in presenting claims for the specified drugs to the Medicare and States' Medicaid Programs, would not and did not

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disclose that the claim amounts included the remuneration prohibited by 42 U.S.C. §1320a-7b(b)(2).

256. The DEFENDANTS' knowing and willful actions in arranging for their customers to receive remuneration prohibited by 42 U.S.C. §1320a-7b(b)(2), in causing the omission of material information from the claims, and in causing the failure to properly disclose and appropriately reflect the remuneration in the claims, caused the claims for the specified drugs to be false and fraudulent claims and caused the claims to be presented to the Medicare and States' Medicaid Programs for payment and approval in violation of 31 U.S.C §3729(a)(1).

257. Because of the DEFENDANTS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of One Billion Dollars (\$1,000,000,000.00) all in violation of 31 U.S.C. §3729(a)(1).

COUNT V

**FALSE CLAIMS ACT; CAUSING A FALSE RECORD OR
STATEMENT TO BE MADE OR USED TO GET
A FALSE OR FRAUDULENT CLAIM PAID OR APPROVED BY THE
GOVERNMENT; ILLEGAL REMUNERATION**

258. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES and on behalf of the Relator, against the Defendants: ABBOTT LABORATORIES, INC.; [REDACTED]

[REDACTED]
[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED], under the **False Claims Act, 31 U.S.C. §§3729-3732.**

259. Relator realleges and incorporates by reference paragraphs 1 through 238 as if fully set forth herein and further alleges as follows:

260. The DEFENDANTS, from on or before June 23, 1989 to the present date, knew that the prices charged to their customers for the specified drugs were significantly reduced in amount from the prices and costs represented by the DEFENDANTS and upon which the DEFENDANTS knew Medicare and Medicaid claims would be approved and paid. Accordingly, the DEFENDANTS have each knowingly offered or paid, or caused to be offered or paid, directly or indirectly, overtly or covertly, in cash or in kind, remuneration to their customers in the form of price reductions and/or in the form of illegal remuneration from the Medicare and/or States' Medicaid Programs to induce them to purchase, order or arrange or to recommend purchasing, arranging or ordering the specified drugs for which

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the DEFENDANTS knew that payment would be made, in whole or in part, by the Medicare and States' Medicaid Programs. Such financial inducement is specifically prohibited by 42 U.S.C. §1320a-7b(b)(2) and 18 U.S.C §2.

261. The DEFENDANTS knew that the Medicare and States' Medicaid Programs would not pay or approve claims for the specified drugs if it were disclosed to the Medicare and States' Medicaid Programs that said claims were for amounts that included remuneration prohibited by 42 U.S.C. §1320a-7b(b)(2).

262. The DEFENDANTS also knew that their customers, in presenting claims for the specified drugs to the Medicare and States' Medicaid Programs, would not and did not disclose that the claim amounts included the remuneration prohibited by 42 U.S.C. §1320a-7b(b)(2).

263. The DEFENDANTS' knowing and willful actions in arranging for their customers to receive remuneration prohibited by 42 U.S.C. §1320a-7b(b)(2), in causing the omission of material information from the claims, and in causing the failure to properly disclose and appropriately reflect the remuneration in the claims, caused the claims for the specified drugs to the false records or statements that were made and used to get a false or fraudulent claim paid or approved by the Government. The DEFENDANTS' actions herein caused said false records or statements to be made and used as prohibited by 31 U.S.C. §3729(a)(2).

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264. Because of the DEFENDANTS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of One Billion Dollars (\$1,000,000,000.00) all in violation of 31 U.S.C. §3729(a)(2).

COUNT VI

**FALSE CLAIMS ACT; CAUSING PRESENTATION OF
FALSE OR FRAUDULENT CLAIMS; PROHIBITED REFERRALS,
CLAIMS AND COMPENSATION ARRANGEMENTS**

265. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES and on behalf of the Relator, against the DEFENDANTS: ABBOTT LABORATORIES, INC.; [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED], under the False

Claims Act, 31 U.S.C. §§3729-3732.

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266. Relator realleges and incorporates by reference paragraphs 1 through 238 as if fully set forth herein and further alleges as follows:

267. The DEFENDANTS, from on or before January 1, 1995 to the present date, knowingly presented or caused to be presented, prohibited claims or bills to individuals and other entities for designated health services [outpatient prescription drugs] furnished pursuant to prohibited referrals from physicians, physician groups and/or outpatient clinics with which the DEFENDANTS had financial relationships, for which the DEFENDANTS knew that payment would be made, in whole or in part, by the Medicare and/or States' Medicaid Programs. Such prohibited referrals, claims, bills and compensation arrangements are specifically prohibited by 42 U.S.C. §1395nn(a)(1)(B) and 18 U.S.C §2.

268. The DEFENDANTS knew that the Medicare and/or States' Medicaid Programs would not pay or approve claims for the outpatient prescription drugs to the Medicare and/or States' Medicaid Programs that said claims were for amounts that included claims or bills prohibited by 42 U.S.C. §1395nn(a)(1)(B).

269. The DEFENDANTS knowingly presented or caused their referring physicians, physician groups and outpatient clinics to present claims or bills for the DEFENDANTS' outpatient prescription drugs to the Medicare and/or States' Medicaid Programs for payment or approval that were false or fraudulent.

270. The DEFENDANTS' knowing actions in having compensation arrangements for its referring physicians, physician groups and outpatient clinics prohibited by 42 U.S.C. §1395nn(a)(1)(B) and in presenting or causing the presentment of prohibited claims in

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violation of 42 U.S.C. §1395nn(a)(1)(B) for payment or approval caused the claims for the outpatient prescription drugs presented to the Medicare and States' Medicaid Programs to be false or fraudulent claims in violation of 31 U.S.C §3729(a)(1).

271. Because of the DEFENDANTS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of One Billion Dollars (\$1,000,000,000.00) all in violation of 31 U.S.C. §3729(a)(1).

COUNT VII

**FALSE CLAIMS ACT; CAUSING A FALSE RECORD OR
STATEMENT TO BE MADE OR USED TO GET
A FALSE OR FRAUDULENT CLAIM PAID OR APPROVED BY THE
GOVERNMENT; PROHIBITED REFERRALS,
CLAIMS AND COMPENSATION ARRANGEMENTS**

272. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES and on behalf of the Relator, against the DEFENDANTS: ABBOTT LABORATORIES, INC.; [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED], under the **False Claims Act, 31 U.S.C. §§3729-3732.**

273. Relator realleges and incorporates by reference paragraphs 1 through 238 as if fully set forth herein and further alleges as follows:

274. The DEFENDANTS, from on or before January 1, 1995 to the present date, knowingly presented or caused to be presented, prohibited claims or bills to individuals and other entities for designated health services [outpatient prescription drugs] furnished pursuant to prohibited referrals from physicians, physician groups and/or outpatient clinics with which the DEFENDANTS had financial relationships, for which the DEFENDANTS knew that payment would be made, in whole or in part, by the Medicare and/or States' Programs. Such prohibited referrals, claims, bills and compensation arrangements are specifically prohibited by 42 U.S.C. §1395nn(a)(1)(B) and 18 U.S.C §2.

275. The DEFENDANTS knew that the Medicare and/or States' Medicaid Programs would not pay or approve claims for the outpatient prescription drugs if it were disclosed to the Medicare and/or States' Medicaid Programs that said claims were for amounts that included claims or bills prohibited by 42 U.S.C. §1395nn(a)(1)(B).

276. The DEFENDANTS knowingly made or used or caused their referring physicians, physician groups or outpatient clinics to make or use false records or statements to get false or fraudulent claims and bills for the DEFENDANTS' outpatient

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prescription drugs to be paid or approved by the Medicare and/or States' Medicaid Programs.

277. The DEFENDANTS' knowing presentment or causing others to present, claims or bills to the Medicare and/or States' Medicaid Programs in violation of 42 U.S.C. §1395nn(a)(1)(B) without disclosing facts revealing said violations constituted the making or using, or the causing others to make or use, false records or statements to get a false or fraudulent claims paid or approved in violation of 31 U.S.C. §3729(a)(2).

278. Because of the DEFENDANTS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of One Billion Dollars (\$1,000,000,000.00) all in violation of 31 U.S.C. §3729(a)(2).

REQUESTS FOR RELIEF

WHEREFORE, the Relator, on behalf of the UNITED STATES, demands that judgment be entered in its favor and against Defendants: ABBOTT LABORATORIES, INC.;

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED], with judgment to be entered against each defendant for the amount of damages: (1) to the States' Medicaid Programs arising from claims for each Defendant's respective specified drugs; and (2) to the Medicare Program arising from claims for those drugs classified under the HCPCS codes covering their specified drugs, jointly and severally with such other defendants whose drugs fall under said HCPCS codes, as follows:

1. On Count I (False Claims Act; Causing Presentation of False Claims) for triple the amount of the UNITED STATES' damages, plus civil penalties of no more than TEN THOUSAND DOLLARS (\$10,000.00) and no less than FIVE THOUSAND DOLLARS (\$5,000.00) for each false claim;

2. On Count II (False Claims Act; Causing False Statements To Be Used To Get False Claims Paid By The GOVERNMENT) for triple the amount of UNITED STATES' damages plus civil penalties of no more than TEN THOUSAND DOLLARS (\$10,000.00) and no less than FIVE THOUSAND DOLLARS (\$5,000.00) for each false statement;

3. On Count III (False Claims Act; causing False Statements To Be Used To conceal An Obligation To Pay Money To The GOVERNMENT) for triple the amount of the UNITED STATES' damages plus civil penalties of no more than TEN THOUSAND

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DOLLARS (\$10,000.00) and no less than FIVE THOUSAND DOLLARS (\$5,000.00) for each false or fraudulent claim paid;

4. On Count IV (False Claims Act; Causing Presentation of False and Fraudulent Claims; Illegal Remuneration) for triple the amount of the UNITED STATES' damages, plus civil penalties of no more than TEN THOUSAND DOLLARS (\$10,000.00) and no less than FIVE THOUSAND DOLLARS (\$5,000.00) for each false claim;

5. On Count V (False Claims Act; Causing A False Record Or Statement To Be Made Or Used To Get A False Or Fraudulent Claim Paid Or Approved by the Government; Illegal Remuneration) for triple the amount of UNITED STATES' damages plus civil penalties of no more than TEN THOUSAND DOLLARS (\$10,000.00) and no less than FIVE THOUSAND DOLLARS (\$5,000.00) for each false statement;

6. On Count VI (False Claims Act; Causing Presentation of False or Fraudulent Claims; Prohibited Referrals, Claims and Compensation Arrangements) for triple the amount of the UNITED STATES' damages, plus civil penalties of no more than TEN THOUSAND DOLLARS (\$10,000.00) and no less than FIVE THOUSAND DOLLARS (\$5,000.00) for each false statement;

7. On Count VII (False Claims Act; Causing a False Record or Statement to be Made or Used to get a False or Fraudulent Claim Paid or Approved by the Government; Prohibited Referrals, Claims and Compensation Arrangements) for triple the amount of the UNITED STATES' damages, plus civil penalties of no more than TEN THOUSAND

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DOLLARS (\$10,000.00) and no less than FIVE THOUSAND DOLLARS (\$5,000.00) for each false statement;

8. For all fees and costs of this civil action; and

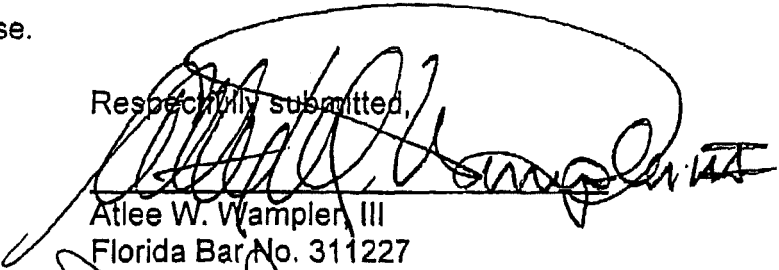
9. For such other and further relief as the Court deems just and equitable.

Further, the Relator, on its behalf, requests that it receive thirty percent (30%), [twenty-five percent (25%) if the United States Government intervenes and proceeds with this case] or such other maximum amount as permitted by law, of the proceeds of this action or settlement of this action collected by the UNITED STATES, plus an amount for reasonable expenses incurred, plus reasonable attorneys' fees and costs of this action. The Relator requests that its percentage be based upon the total value recovered, including any amounts received from individuals or entities not parties to this action.

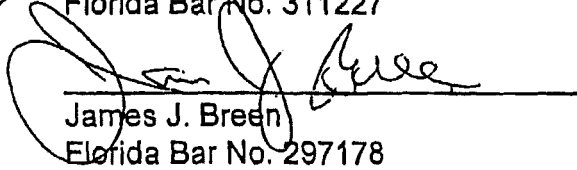
DEMAND FOR JURY TRIAL

A jury trial is demanded in this case.

Respectfully submitted,



Atlee W. Wampler, III
Florida Bar No. 311227



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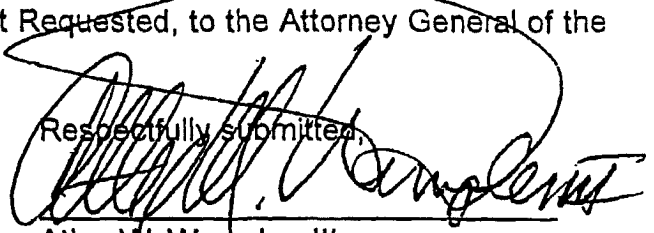
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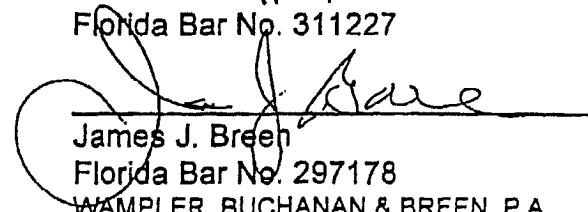
CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 9th day of December, 1999, I caused an original and a copy of this Third Amended Complaint to be filed under seal and in camera for sixty (60) days and not to be served on the Defendants named herein or until further order of this Honorable Court.

I HEREBY CERTIFY that prior to this 9th day of December, 1999, I caused a copy of this Third Amended Complaint and written disclosure of substantially all material evidence and information the Relator, VEN-A-CARE possesses to be served on the Government pursuant to Rule 4(i), Fed.R.Civ.P., prior to the filing of this Third Amended Complaint by delivering a copy of the Summons, Third Amended Complaint, material evidence and information to the United States Attorney for the Southern District of Florida, and by sending a copy of the Summons, Third Amended Complaint, material evidence and information by Certified Mail, Return Receipt Requested, to the Attorney General of the United States in Washington, D.C.

Respectfully submitted,


Atlee W. Wampler, III
Florida Bar No. 311227


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